Exhibit 1

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

SOUTH WIND WOMEN'S CENTER LLC, d/b/a TRUST WOMEN OKLAHOMA CITY, on behalf of itself, its physicians and staff, and its patients, et al.,	)	
Plaintiffs,	)	
v.	)	
J. KEVIN STITT in his official capacity as Governor of Oklahoma, et al.,	)	Case No. CIV-20-277-G
Defendants.	)	

REBUTTAL DECLARATION OF MARK NICHOLS, M.D.

I, Mark Nichols, M.D., declare as follows:

Background

1. I am a board-certified obstetrician-gynecologist ("OB/GYN") licensed to practice medicine in the State of Oregon. For more than three decades, I have provided the full range of gynecological and obstetric care, including contraception, prenatal, labor and delivery, and postpartum care, as well as abortion care, to thousands of patients. During that time, I have delivered at least 3,000 babies. In many cases, I have provided abortion and obstetrics care to the same woman at different points in her life.

2. I earned my medical degree from the University of California, Davis in 1979, and completed my residency in the Department of Obstetrics and Gynecology at Oregon Health Sciences University ("OHSU") in 1983. I have been certified by the American Board of Obstetrics and Gynecology since 1985 and have been a Fellow of the American College of Obstetrics and Gynecology ("ACOG") since 1986.

3. I am currently a Professor of Obstetrics and Gynecology at OHSU and the Director Emeritus of OHSU's Family Planning Fellowship. I previously served as the Assistant Director of

OHSU's OB/GYN Residency Training Program, and I have trained over 200 Obstetrics and Gynecology medical residents and fellows over the course of my career. In addition to my academic and administrative roles at OHSU, I served as the Medical Director and Co-Medical Director of Planned Parenthood Columbia Willamette affiliate from 1994 to 2013 and was a member of Planned Parenthood Federation of America's ("PPFA") National Medical Committee from 1996 to 2002. PPFA's National Medical Committee develops clinical policy and protocols for more than 500 health centers run by Planned Parenthood affiliates around the country. I currently serve on the PPFA National Board of Directors.

4. On numerous occasions since 2010, I have provided medical, consulting, and teaching services abroad through Médecins Sans Frontières (Doctors Without Borders) and other organizations in Ethiopia, Ghana, Laos, Nigeria, South Sudan, Tanzania, Vietnam, and Zambia. In 2013, I semi-retired by reducing my time at OHSU by 50 percent, which allows more time to focus on my international work. I continue to see approximately 80 obstetrics patients per month at OHSU, where I also continue to provide abortion care and train OHSU fellows and residents to provide abortion care. Since 2013, I have provided abortions at Planned Parenthood Columbia Willamette on an as-needed basis.

5. I have authored and co-authored dozens of peer-reviewed research articles and chapters in medical textbooks on a variety of women's health issues, including contraception, menstruation, cancers, pregnancy, delivery, and abortion. In addition, I have lectured nearly 200 times at local, national, and international professional conferences and universities.

6. I am a member of numerous professional societies and committees, including the Association of Reproductive Health Professionals, ACOG, and the National Abortion Federation, and serve in several appointed or elected positions within those groups. I am a founding member

of the Society of Family Planning ("SFP"), an academic society devoted to promoting high-quality, evidence-based research in the area of reproductive health and family planning, and I served as President of the SFP Board of Directors from 2009–2011. I am also a journal reviewer for the *American Journal of Obstetrics and Gynecology*, *Obstetrics and Gynecology*, *Journal of American Women's Association*, *British Journal of Obstetrics and Gynecology*, *New England Journal of Medicine*, and the *International Journal of Obstetrics and Gynecology*.

7. A copy of my curriculum vitae setting forth my experience, education, and credentials in greater detail is attached as Exhibit 1-1.

8. I understand that Oklahoma has an Executive Order that mandates the postponement of "elective surgeries" and "minor medical procedures," and that, as of March 27, Oklahoma has extended that Executive Order to apply to all abortion services in Oklahoma. As a result, I understand that the state's position is that the Executive Order requires all abortions be postponed in Oklahoma at least through April 30. I also understand that on April 6, the Court ordered that the prohibition on medication abortion cannot be enforced, and that the prohibition on abortion procedures cannot be enforced as to pregnant people who will lose their right to lawfully obtain an abortion in Oklahoma on or before April 30.

9. I have reviewed the declarations of Drs. Valley, Harrison, Haney, Mareshie, and Sanders, and respond to their assertions in more detail below. I understand that Dr. Harrison's declaration is identical to the submission she made in another case, to which Dr. Daniel Grossman submitted a thorough rebuttal. I have reviewed Dr. Grossman's rebuttal declaration, which is attached as Exhibit 1-2.

10. I have also reviewed the opinions of the American College of Obstetricians and Gynecologists ("ACOG"), the American Medical Association ("AMA"), and other nationwide medical organizations set forth in an amicus brief to the Fifth Circuit Court of Appeals in a case

involving Texas's application of its COVID-19 order to abortion care in that state. The amicus brief is attached as Exhibit 1-3.

11. Because of the emergency nature of these proceedings, I have focused my opinions on issues that I understand are pertinent to Plaintiffs' pending motion for preliminary injunctive relief. I have numerous other disagreements with Oklahoma's declarants, and I reserve the right to supplement my opinions in further stages of these proceedings.

Overview of Opinions

12. I disagree with Oklahoma's claim that the mandatory postponement of abortion services does not harm patients in the state. Oklahoma's position that all abortion services be postponed at least through April 30 denies pregnant people access to legal abortion care in Oklahoma. As a result, some pregnant people effectively will be banned from obtaining a wanted abortion. People who are delayed in accessing abortion care suffer a range of harms, including unnecessary health risks, more limited and burdensome medical options, physical and psychological harms related to prolonged pregnancy, and potentially heightened risks in the event of COVID-19 infection.

13. I disagree with Oklahoma's claim that the mandatory postponement of abortion services furthers the state's public health objectives. Requiring that most abortion procedures be postponed at least through April 30 is not likely to conserve resources needed to address COVID-19, including hospital resources, nor reduce the spread of COVID-19 by reducing in-person interactions with the health care system. Pregnant patients need medical care, whether that care is abortion care, prenatal care, or delivery. People who are forced to remain pregnant and do not access abortion care between now and April 30 will have a variety of health care needs, including prenatal care, that should not be postponed and cannot be provided through telemedicine. This

care, which will be required in the short-term, requires in-person visits with health care providers and medical resources to the same or greater extent than abortion care.

14. Whether or not a pregnant person ultimately terminates their pregnancy, remaining pregnant means continuing to experience pregnancy symptoms and risk pregnancy complications. Pregnant people are likely to have unscheduled contacts with the health care system, including emergency room (ER) visits. In light of COVID-19, pregnant people are likely to make additional visits to the ER; while much is unknown about COVID-19, current recommendations indicate that pregnant people who are suspected of having COVID-19 be referred to the ER. This is in contrast to recommendations to non-pregnant people, who are advised to remain at home unless their symptoms are severe.

15. If Oklahoma's ban on abortion care extends beyond April 30, patients forced to remain pregnant will have additional health care needs, whether or not they ultimately terminate a pregnancy. For patients that seek prenatal care, longer-term prenatal services will require medical resources and in-person contacts that far exceed abortion care.

16. I disagree with Oklahoma's claim that nearly all abortion services are elective and capable of being postponed. Abortion care is time-sensitive and essential health care, with a well-documented safety record and low complication rate, that should not be delayed during COVID-19. In the rare event of a complication, most can be managed in an outpatient—non-hospital—setting.

17. I disagree with Oklahoma's claim that the risks of abortion care are understated or unknown. Abortion care is safe, and its exceptionally low rate of complications is well-documented and validated by leading medical authorities.[1]

[1] Nat'l Acads. Sci., Eng., and Med., *The Safety and Quality of Abortion Care in the United States*, at 10, 77-78 (2018) [hereinafter Nat'l Acads.], attached as Exhibit 1-4.

Applying the Executive Order to Require Postponing Most Abortion Procedures Will Harm Patients in the Short-Term

18. Contrary to the assertions by the state's declarants that abortion is "elective,"[2] abortion is a time-sensitive, essential health service that should not be delayed during the COVID-19 crisis. In fact, ACOG and other leading medical organizations recently stressed in a joint statement, "Abortion Access During the COVID-19 Outbreak," abortion "is an essential component of comprehensive health care" and "a time-sensitive service for which a delay of several weeks, or in some cases days, may increase the risks [to patients] or potentially make it completely inaccessible."[3]

19. Pregnancy has a duration of approximately 40 weeks, as measured from the first day of a woman's last menstrual period ("LMP"). Consequently, the term I will use in reference to the gestational age of the pregnancy is XX weeks LMP. I understand that in Oklahoma abortion is almost entirely banned about halfway through pregnancy, after 22 weeks LMP.

20. I understand that, as a result of the Court's temporary restraining order, patients seeking medication abortion and patients who would be pushed beyond Oklahoma's legal limit are not currently required to postpone their abortion care, but other patients—patients seeking abortion procedures who in theory could obtain a legal abortion upon expiration of the Executive Order—are still subject to the mandatory postponement requirement. Even with the Court's current order in place, pregnant patients will be harmed.

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[2] *See, e.g.*, Decl. Michael T. Valley, M.D. ("Valley Decl.") ¶ 12, ECF No. 54-4.

[3] ACOG, *Joint Statement on Abortion Access During the COVID-19 Outbreak* (Mar. 18, 2020), https://www.acog.org/news/news-releases/2020/03/joint-statement-on-abortion-access-during-the-covid-19-outbreak, attached as Exhibit 1-5; *see also* Brief for ACOG, AMA, et al., Amici Curiae in Opposition to Texas Petition for Writ of Mandamus, *In re Paxton*, No. 20-50264 (Apr. 2, 2020), *mandamus granted*, 2020 WL 1685929 (5th Cir. April 7, 2020), https://www.acog.org/-/media/project/acog/acogorg/files/advocacy/amicus-briefs/20200402-5th-cir-20-50264-acog-ama-amicus.pdf?la=en&hash=D5BF60E9D4FD6693DE6CAEFECA25E184.

21. Medication abortion is approved by the FDA until 10 weeks (70 days) LMP. There is good evidence that medication abortion is safely provided beyond 10 weeks LMP, and some providers offer this option as an off-label use of the medication, a common practice of all health care providers.[4] For some patients early in pregnancy, however, medication abortion may not be appropriate, including because they have an allergy to the medications used or a medical condition that makes a suction abortion procedure comparatively safer for them.[5]

22. Additionally, under the Court's temporary restraining order, abortion continues to be prohibited for patients who require an abortion procedure, but who will not be 22 weeks LMP as of April 30. This includes all patients who, as of April 9, are between 11 and 19 weeks LMP. These patients will be forced to continue their pregnancies during the Executive Order, and either: delay abortion by at least several weeks or travel to another state to access legal abortion care.

23. Pregnancy carries risk, and delaying abortion forces a pregnant person to remain pregnant longer, experiencing the symptoms, risks, and potential complications of pregnancy. Even an uncomplicated pregnancy stresses a pregnant person's body, affects every organ system, and increasingly compresses abdominal organs as pregnancy progresses. Beginning in early pregnancy, a pregnant person's breathing can change as a result of hormonal changes and the uterus expanding—making many pregnant people feel short of breath. A pregnant person's heart and the lungs work harder, to pump blood throughout the body and to remove carbon dioxide from her body and the fetus. Pregnancy also causes the body to produce more clotting factors, predisposing the pregnant person to blood clots and to venous thromboembolism—a condition in

[4] *See* Nat'l Abortion Fed., *Clinical Policy Guidelines for Abortion Care*, 16-17 (2020), https://5aa1b2xfmfh2e2mk03kk8rsx-wpengine.netdna-ssl.com/wp-content/uploads/2020-CPGs-Final-for-web.pdf.

[5] U.S. Food & Drug Admin., Mifeprex Label at 1 (approved Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf (medication abortion should not be provided to certain people, including those with an IUD in place, allergy to mifepristone or misoprostol, or conditions such as chronic adrenal failure, hemorrhagic disorders or concurrent anticoagulant therapy) [hereinafter Mifeprex Label], attached as Exhibit 1-6; *see also* Nat'l Acads. at 51.

which a blood clot forms in the veins of the leg, arm, or groin, or travels to the lungs and can be life-threatening throughout pregnancy.

24. Delay is also problematic for people for whom pregnancy worsens underlying health conditions or who seek abortion care for a variety of health reasons. Pregnancy can exacerbate conditions including diabetes and hypertension. Gestational diabetes, gestational hypertension-related conditions, including preeclampsia, and hyperemesis gravidarum (which causes severe pregnancy-related nausea and vomiting) can arise simply because a person is pregnant. For patients suffering these conditions, it can be especially cruel to prevent them from getting the medical treatment they need.

25. Requiring a person to delay abortion care also targets a safe procedure and ultimately makes it less safe. Though abortion is extremely safe, the risks increase incrementally as pregnancy progresses, as does the invasiveness of the procedure and the potential need for sedation.[6]

26. Depending on a physician's training, beginning at approximately 15-16 weeks LMP, the physician will perform a dilation and evacuation ("D&E"), rather than a suction aspiration, procedure. While the complication rate is still low, because D&E uses additional instruments, is comparatively more complex than aspiration, and is generally performed at a later gestational age, the risk of complication is comparatively greater than for abortion procedures performed earlier.[7] Additionally, because there is more blood flow to the uterus as pregnancy progresses, there can be more bleeding associated with an abortion procedure later in pregnancy.[8]

[6] Nat'l Acads. at 10-11.
[7] *See, e.g.*, Nat'l Acads. at 65.
[8] *See* Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstet. & Gynecol. 175, 180 (2015), attached as Exhibit 1-7.

27. Delay can also mean the difference between a one-day or a two-day procedure. In the early part of the second trimester, through approximately 18 to 20 weeks LMP, many physicians perform cervical preparation and uterine evacuation on the same day. Later in the second trimester, depending on the method of cervical preparation, the physician may start the dilation process earlier—one day before the evacuation. On the first day, the patient visits the clinic and physician begins dilation that will continue overnight, and on the second day, the patient returns to the clinic for her procedure.

28. An abortion procedure later in pregnancy is also more likely to involve sedation. If sedation is used, it is routine to require that another person accompany the patient to the clinic so that they can drive the patient home following the procedure. In light of COVID-19, this risks exposing an additional person to the virus. And, for patients who wish to conceal their pregnancy, the requirement that someone accompany them for abortion care can be particularly challenging.

29. For other patients, being forced to continue with an unwanted pregnancy due to delays causes psychological harm. Patients may need to conceal the pregnancy from an abusive or controlling partner or others who would disapprove or shame them. Remaining pregnant against one's will is also a unique form of psychological harm. Some pregnant people, faced with these realties, may even attempt to self-manage an abortion, creating the potential for great harm.[9]

30. Finally, delay can be especially upsetting to patients terminating wanted pregnancies due to lethal or severe fetal anomalies, including, as discussed in more detail below, anomalies that can be detected by tests that are performed between 11 and 16 weeks LMP. These abnormalities can range from mild to incompatible with life and impact a pregnant person's decision about whether to continue her pregnancy.

[9] *See, e.g.*, Jenna Jerman et al., *Barriers to Abortion Care and Their Consequences for Patients Traveling for Services: Qualitative Findings from Two States*, 49(2) Persp. on Sexual & Reprod. Health 95, 101 (2017).

31. To put this in perspective, consider, for example, a patient who was 10.0 weeks LMP on March 27, the day the Executive Order effectively banned abortion care. Had she been able to access abortion care on March 27, she could have had a medication abortion or a straightforward suction aspiration abortion procedure. The Court's April 6 temporary restraining order does not help her: by April 6, she was 11 weeks and 3 days LMP, and ineligible for medication abortion. When the Executive Order expires as scheduled on April 30, she will be approximately 15 weeks LMP. She will have been forced to remain pregnant an additional 5 weeks, which imposes the harms I describe above. If she is able to access abortion at 15 weeks LMP, she will not be able to have a medication abortion, and her only option will be an invasive abortion procedure.

32. If the Executive Order is extended an additional month, this same patient will be forced to continue her pregnancy until at least May 30, when she will be approximately 19 weeks LMP. Even if the Court's current order is also extended, it will not help her. She will have been forced to remain pregnant for an additional 9 weeks, with the risks and harms of delay described above. If she is able to access abortion on May 30, she will have a D&E procedure, which will likely take place over two days, and carries the incrementally increased risk compared to an earlier abortion, as I discussed above. Of course, delaying a patient into this later abortion procedure does not serve the Executive Order's interests—two visits will require more PPE by clinic staff and the patient, and additional in-person contact.

33. Additionally, contrary to the state's suggestions, requiring a pregnant person to postpone her abortion by 5 or 9 weeks does not mean she should go without health care during that time. Pregnancy carries risk, and, as discussed further below, pregnant people, including those

who are not certain whether and when they will be able to obtain abortion care require care to monitor their health during their pregnancy.

Pregnant People Forced to Remain Pregnant Require Health Care in the Short-Term

34. I understand that Oklahoma claims that applying the Executive Order to all abortion services will ease the strain on the health care system and reduce PPE use. This contention ignores that pregnant women who are denied or delayed in accessing abortion care will remain pregnant, and pregnant women require health care—including health care in the short-term.

35. I have reviewed the declarations submitted by Drs. Valley, Haney, Mareshie, and Sanders, and Ms. Adams, which Oklahoma submits in support of this argument. Specifically, Dr. Valley states that for women who do not have high-risk pregnancies, some prenatal visits can be temporarily postponed or conducted via telehealth.[10] Dr. Sanders likewise asserts that prenatal care as a general matter can be delayed or conducted via telehealth.[11] Dr. Mareshie suggests without support that postponing abortion care will prevent the depletion of PPE.[12] Drs. Valley and Sanders also state that the majority of PPE is not needed during pregnancy until the end of pregnancy, for childbirth—suggesting that postponing abortion care will preserve PPE and hospital resources in the short-term.[13] And, Ms. Adams states that the center for which she works is "telling women not to seek prenatal services unless they have an actual medical problem or emergency."[14]

36. Based on my knowledge, experience, and familiarity with the relevant medical literature, I disagree with those assertions. As detailed below, while *some* prenatal visits may be safely postponed or conducted via telemedicine in light of the COVID-19 public health emergency,

[10] Valley Decl. ¶ 8, ECF No. 54-4.
[11] Decl. Rita Sanders, D.O. ("Sanders Decl.") ¶ 6, ECF No. 54-8.
[12] Decl. Christy J. Mareshie, D.O. ("Mareshie Decl.") ¶¶ 7–8, ECF No. 54-2; *see also* Decl. Jeremy Haney, M.D. ("Haney Decl.") ¶ 7, ECF No. 54-3. Dr. Haney does not specifically mention abortion but discusses "elective" procedures and submitted a declaration in support of Oklahoma's position.
[13] Valley Decl. ¶ 11, ECF No. 54-4; Sanders Decl. ¶ 6, ECF No. 54-8.
[14] Decl. Kathy Adams, R.N. ("Adams Decl.") ¶ 9, ECF 75-2.

certain prenatal care, including care within the first 22 weeks of an uncomplicated pregnancy, should *not* be postponed and will require in-person visits to a clinician in the short-term.

37. Pregnancy is not a static condition. Pregnant patients need medical care, whether that care is abortion care, prenatal care, or delivery. In fact, Oklahoma encourages pregnant people to obtain prenatal care and emphasizes the importance of prenatal care for the health of the pregnant person and the fetus.[15] While this guidance may shift in light of COVID-19, accessing prenatal care remains important for the health of the pregnant person and the fetus.

38. For uncomplicated first pregnancies, a patient typically visits their provider every 4 weeks during the first and second trimesters (to 28-eight weeks), every 2 weeks until 36 weeks, and every week from 36 weeks to delivery.[16] For a patient who begins prenatal care at 8 weeks, the patient will have approximately 14 visits with their prenatal care provider, including delivery, with approximately 4 to 6 of those occurring before 22 weeks LMP.

39. At an initial prenatal care visit, which is recommended at approximately 8 to 10 weeks, a patient will typically have a physical exam (including a pelvic exam and a pap smear, if indicated), blood tests, urine culture, STD screening, and an ultrasound to confirm the gestational age of the pregnancy. Throughout pregnancy, patients make additional in-person visits for physical

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[15] *See, e.g.*, Okla. Health Care Auth., *Tips for Being Healthy While You are Pregnant*, http://www.okhca.org/individuals.aspx?id=712&menu=48 (last visited April 9, 2020) ("See a doctor or clinic as soon as you think you are pregnant. Keep all prenatal appointments with your doctor or health care provider."); Okla. Health Care Auth., *What to Expect At Your Prenatal Care Visits*, http://www.okhca.org/individuals.aspx?id=708&menu=48 (last visited April 9, 2020) (explaining that the first prenatal care visit entails a physical exam, including "[b]lood pressure and temperature checks[; m]outh and teen exam[; b]reast exam[; p]elvic exam[; p]ap smear[; b]lood and urine tests," and later prenatal visits include "[w]eight and blood pressure checks[; m]easuring the baby's growth[; c]hecking the baby's heart rate[; s]pecial tests you may need to find out about your health or the health of your baby [and p]hysical exams as needed"); Okla. Health Care Auth., *Warning Signs During Pregnancy*, http://www.okhca.org/individuals.aspx?id=714&menu=48 (last visited April 9, 2020) ("It is important to see your doctor often and regularly." Directs pregnant people to call their doctor right away upon seeing certain signs, including vaginal bleeding, sharp stomach pain, pain while urinating, and less movement of the fetus after the fifth month of pregnancy).

[16] *See, e.g.*, Off. on Women's Health in the U.S. Dep't of Health & Human Servs., *Prenatal Care and Tests*, https://www.womenshealth.gov/pregnancy/youre-pregnant-now-what/prenatal-care-and-tests (last updated Jan. 30, 2019).

exams, including pelvic exams; genital cultures; ultrasounds; and blood draws to assess the condition of the pregnant patient. Prior to COVID-19, each required the use of, at least, one pair of disposable gloves for each clinician the patient sees.

40. Between approximately 11-13 weeks, a patient is offered a more detailed ultrasound and a blood draw, to screen for fetal or genetic abnormalities. Based on the results of this ultrasound, a patient may be referred to a maternal-fetal medicine specialist or a medical geneticist for consultation about the significance of the findings and discussion of options for the woman.

41. At approximately 18-22 weeks LMP, the patient routinely has another more extensive and lengthier ultrasound to evaluate the anatomy of the fetus in greater detail. This more detailed ultrasound scan is usually performed at a hospital or special ultrasound facility, rather than in a private clinician's office. The scan usually reassures a pregnant person that their fetus has no detectable anomalies, but some fetuses will have abnormalities ranging from mild to incompatible with life. Based on the results of this scan, patients will consult with their prenatal providers and consultants about their options. Follow up ultrasound evaluations or other imaging techniques such as MRI may be used to evaluate the fetus and provide guidance about the severity and prognosis of the fetal condition. In the case of anomalies incompatible with life, termination of pregnancy is discussed with the patient. The risk to the pregnant person's life and health is far greater from carrying the pregnancy to term, compared to terminating the pregnancy at that point.

42. The location and growth of the placenta is also evaluated at 18-22 weeks LMP using ultrasound. The placenta may be found to invade a previous cesarean section scar, a condition called placenta accreta. In these cases also, termination of pregnancy is discussed with the pregnant woman as it is safer for her compared to carrying the pregnancy to term.

43. Genetic testing occurs at various times during the pregnancy. Cell-free DNA testing, which is done to screen for various genetic conditions, is conducted early in pregnancy. This test involves obtaining a blood sample from the woman, usually at about 11-12 weeks LMP. Additional genetic tests, which require blood draws, are done between 11 and 22 weeks LMP. For example, chorionic villus sampling (CVS), which analyzes a biopsy from the placenta for abnormalities, is provided between 10 and 13 weeks LMP. This is performed by inserting a plastic catheter through the cervix into the placenta under ultrasound guidance. Amniocentesis, which analyzes fetal cells in an amniotic fluid sample taken from the gestational sac, is conducted at approximately 16 weeks LMP and involves insertion of a needle into the uterus. Both of these procedures carry the risk of complications, including infection, miscarriage, and preterm labor.

44. Some pregnant patients require more, or different, prenatal care, if there is a complication or the patient is high risk. Risk factors for high-risk pregnancies include prior complicated pregnancies, pre-existing maternal medical conditions such as advanced maternal age, hypertension, heart disease, diabetes, obesity, and pregnancy abnormalities such as multiple gestation, placental abnormalities, or threatened miscarriage.

45. In light of the COVID-19 public health emergency, ACOG, the Society of Maternal Fetal Medicine, and other experts have issued guidance to assist providers in postponing or reducing the number of in-person visits where possible and to shift certain care to telehealth.[17] We have adopted these guidelines at OHSU.

[17] *See, e.g.*, ACOG, *Examples of Alternate or Reduced Prenatal Care Schedules* (Mar. 24, 2020), https://www.acog.org/clinical-information/physician-faqs/-/media/287cefdb936e4cda99a683d3cd56dca1.ashx [hereinafter ACOG, *Alternate or Reduced Prenatal Care*]; ACOG, *COVID-19 FAQs for Obstetrician-Gynecologists, Obstetrics*, https://www.acog.org/clinical-information/physician-faqs/covid-19-faqs-for-ob-gyns-obstetrics (last visited April 9, 2020); Rupsa C. Boelig et al., *MFM Guidance for COVID-19*, Am. J. Obstet. & Gynecol. (Mar. 19, 2020), https://www.sciencedirect.com/science/article/pii/S2589933320300367?via%3Dihub.

46. Based on that guidance, pregnant patients are still advised to make at least two in-person visits for prenatal care during the first 22 weeks of an uncomplicated pregnancy. These visits should not be postponed and cannot be provided by telemedicine. At a minimum, during COVID-19, it is recommended that patients have their initial obstetric labs between approximately 11-13 weeks LMP, including blood tests, urine culture, STD screening, as well as a physical exam including a pelvic exam.[18] Patients also have two important ultrasounds—an ultrasound between 11-13 weeks LMP, for pregnancy dating and to screen for abnormalities, and an anatomy scan between 18-22 weeks LMP.[19]

47. The ultrasound at 11-13 weeks LMP is critical in establishing the due date of pregnancy. The accuracy of establishing the gestational age, and thus the projected due date decreases significantly as the pregnancy progresses. All prenatal care guidelines are based on the gestational age of the patient. For example, knowing an accurate due date enables the prenatal provider to advise when induction of labor is indicated if the patient goes beyond their due date. Pregnancies that continue longer than the due date are at increased risk of stillbirth and intervening based on an accurate due date greatly reduces this risk. During this ultrasound, the clinician wears gloves. In light of COVID-19, the clinician also wears a mask consistent with Centers for Disease Control and Prevention (CDC) guidelines.

48. The 18-22 week anatomy scan is also critical. As noted above, this scan can detect conditions that endanger the pregnant person's health or life, and therefore have consequences for her future care. Two to three clinicians are involved in this visit, including a radiology technician, radiologist, and/or maternal-fetal medicine specialist. Each wears a pair of gloves, and, in light of COVID-19, additional PPE including a mask consistent with CDC recommendations.

[18] Boelig et al. at 5; ACOG, *Alternate or Reduced Prenatal Care*.
[19] Boelig et al. at 5; ACOG, *Alternate or Reduced Prenatal Care*.

49. In sum, for an uncomplicated pregnancy during COVID-19, pregnant patients will still make at least 2-3 in-person visits within the first 22 weeks of pregnancy. Each of these visits requires PPE and interaction with at least one clinician; although each interaction can risk spreading COVID-19, that must be balanced with the provision of essential care.

50. Contrary to the state's suggestion, pregnant people who want to end a pregnancy but are subject to the Executive Order's mandatory postponement requirement should not be advised to stay out of the health care system.[20] As discussed above, pregnancy carries risks and can exacerbate underlying medical conditions. Accordingly, leading medical authorities continue to advise that pregnant people access prenatal care, including in early pregnancy, as such care is important to assess a pregnant person's health. For pregnant people subject to the Executive Order's mandatory postponement requirement, my medical advice would be to visit a medical provider to assess health status and discuss options, as well as to have an ultrasound performed to establish gestational age.

51. Pregnant people are also not immune from seeking or needing emergency room care during their pregnancy. In fact, medical literature reports that 20% of pregnant patients will visit an emergency room at least once during their pregnancy. Among those who visit an emergency room, between approximately 29% will have two or more visits.[21] In my experience, much pregnancy-related emergency room care is in the first trimester of pregnancy, for people experiencing miscarriage. And, miscarriage is common: approximately 10% of pregnancies end in

[20] Adams Decl. ¶ 9, ECF 75-2.

[21] *See, e.g.*, Shayna D. Cunningham et al., *Association Between Maternal Comorbidities and Emergency Department Use Among a National Sample of Commercially Insured Pregnant Women*, 24 Acad. Emergency Med. 940, 942 (2017); *see also* Urania Magriples et al., *Prenatal Health Care Beyond the Obstetrics Service: Utilization and Predictors of Unscheduled Care* 198 Am. J. of Obstet. & Gynecol. 75.e1, 75.e5 (2008).

miscarriage in the first trimester[22] and approximately 1-5% of pregnancies end in miscarriage between 13 to 19 weeks LMP.[23]

52. Additionally, although much is unknown about COVID-19, pregnant people also may be at increased risk of having severe COVID-19 infections and must take precautions.[24] Accordingly, ACOG and the Society for Maternal Fetal Medicine issued guidance for assessing and managing pregnant patients with suspected or confirmed COVID-19.[25] The assessment tool recommends referring a pregnant person to the ER if they present with a variety of symptoms, including difficulty breathing, dizziness, or inability to keep liquids down. Each of these symptoms may be routine pregnancy symptoms or symptoms of COVID-19. Regardless, given the uncertainty with concerning symptoms, experts recommend referring pregnant patients to the emergency room, which will increase strain on hospital resources. These recommended referrals to the ER apply to pregnant people with wanted pregnancies as well as those who are unable to obtain abortion care, who, if forced to remain pregnant continue to risk the complications of pregnancy and experience pregnancy symptoms.

53. In contrast, the CDC recommends that the general public (i.e., people who are not pregnant) and experiencing COVID-19 symptoms stay at home and only visit the hospital if their symptoms are severe.[26] To put this in perspective, for each woman denied a wanted abortion, and

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[22] ACOG, *ACOG Practice Bulletin: Early Pregnancy Loss*, 132 Obstet. & Gynecol. e197, e197 (Nov. 2018), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/11/early-pregnancy-loss.

[23] Thomas C. Michels et al., *Second Trimester Pregnancy Loss*, 76(9) Am. Fam. Physician 1341, 1341 (Nov. 2007), https://www.aafp.org/afp/2007/1101/p1341.html.

[24] *See* CDC, *Pregnancy and Breastfeeding FAQs*, *Information about Coronavirus Disease 2019*, https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnancy-breastfeeding.html (last visited Apr. 3, 2020), attached as Exhibit 1-8.

[25] ACOG & Soc'y for Maternal Fetal Med., *Outpatient Assessment and Management for Pregnant Women With Suspected or Confirmed Novel Coronavirus (COVID-19)* (Mar. 2020), https://www.acog.org/-/media/project/acog/acogorg/files/pdfs/clinical-guidance/practice-advisory/covid-19-algorithm.pdf?la=en&hash=2D9E7F62C97F8231561616FFDCA3B1A6, attached as Exhibit 1-9.

[26] CDC, *What to Do if You Are Sick*, https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html (last visited Apr. 5, 2020).

therefore forced to continue her pregnancy, there may be one additional person who, when they have some sign of possible COVID-19 infection, will be sent to the ER rather than to isolate at home.

54. Additionally, the rate at which people obtain emergency room care following an abortion is very low. Abortion-related ER visits make up only 0.01% of all ER visits,[27] and only 0.87% of abortions result in an emergency room visit at which the patient receives a diagnosis, treatment, or diagnosis and treatment for an abortion-related reason.[28]

Pregnant People Will Require Health Care in the Longer-Term

55. If the Executive Order is extended beyond April 30, a pregnant person who is denied a wanted abortion and forced to continue a pregnancy will continue to experience pregnancy symptoms, risk pregnancy complications, and have additional contacts with the health care system.

56. Dr. Valley states that the "majority of PPE isn't needed during pregnancy until the end of pregnancy, for childbirth," and speculates that "for the patients involved here, that moment is several months away, which will, I hope be beyond the shortage caused by the pandemic."[29] However, the duration of the public health emergency is unknown, and experts anticipate could last a year to 18 months.[30] Pregnant people will continue to need health care during that time, and, if unable to access abortion care, will be forced to carry their pregnancies. Beyond 22 weeks LMP, pregnancy care includes additional tests and one or two ultrasounds to assess the health of the patient and the fetus.

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[27] Ushma D. Upadhyay et al., *Abortion-Related Emergency Room Visits in the United States: An Analysis of a National Emergency Department Sample*, 16(1) BMC Med. 1, 1 (2018), attached as Exhibit 1-10.
[28] Upadhyay (2015) at 177.
[29] Valley Decl. ¶ 11, ECF No. 54-4.
[30] *See, e.g.*, Peter Baker & Eileen Sullivan, *U.S. Virus Plan Anticipates 18-Month Pandemic and Widespread Shortages*, N.Y. Times (Mar. 17, 2020), https://www.nytimes.com/2020/03/17/us/politics/trump-coronavirus-plan.html.

57. Labor and delivery require significant amounts of PPE, particularly given the number of medical staff involved in even uncomplicated deliveries, and hospital resources. For a vaginal delivery, the patient will be assisted by, at the very least, a physician or midwife, as well as one nurse for the delivering person, and one nurse for the newborn. Frequently, there will be additional personnel assisting throughout the delivery if the labor has become complicated. The primary clinicians must wear PPE, including gowns, gloves, shoe covers, and often surgical masks. After an uncomplicated vaginal delivery, the patient and the baby typically remain in the hospital for about 24-48 hours.

58. Delivery by cesarean section ("C-section"), which occurs in about 30% of deliveries in the United States, requires substantially more staff and more PPE than vaginal delivery, as a C-section is a major abdominal surgery with an inpatient recovery period of two to four days. For a C-section, personnel involved will generally include an OB/GYN, an assistant, a scrub tech, a circulating nurse, an anesthesiologist, and very possibly a neonatal team. Each of these personnel generally wear PPE, including surgical masks and gloves, with some wearing gowns and shoe covers as well.

59. For deliveries for patients with confirmed or suspected COVID-19 infection, all personnel would wear full PPE, including masks, gloves, gowns, shoe covers, and face shields.

Abortion is Common, Safe, and Essential Health Care

60. Drs. Valley and Harrison also offer opinions about the safety of abortion and abortion complications that are contrary to robust, mainstream medical literature. Dr. Sanders also notes without elaboration that she has seen abortion complications in her private practice and as an emergency physician, and that "[c]omplications might require hospital space."[31]

[31] Sanders Decl. ¶ 8, ECF No. 54-8.

61. Contrary to these assertions, abortion is an extremely safe and straightforward medication regimen or procedure. Both carry a low risk of complications and a very low risk that hospitalization is necessary to treat a complication.[32] As an initial matter, I understand that Dr. Harrison's declaration is identical to the submission she made in another case, and to which Dr. Daniel Grossman responded in a thorough rebuttal. I have reviewed Dr. Grossman's rebuttal declaration and agree with its key points, including that Dr. Harrison has misstated and exaggerated the risks of medication abortion. I focus below on the mischaracterizations or inaccuracies in Dr. Harrison's declaration that are most relevant here.

62. First, to the extent Dr. Harrison discusses complication rates, she states that true complication rates are unknown, when, in fact, the safety of abortion is well documented. Indeed, the safety of abortion has been repeatedly confirmed by multiple peer-reviewed studies in highly respected journals. A recent, robust analysis of the full range of abortion care in the United States performed by the National Academies of Sciences, Engineering, and Medicine (National Academies), a body of esteemed experts that was established by Congress to provide independent, objective expert analysis and advice to the nation to inform public policy and "focused on finding reliable, scientific information," concluded that abortion continues to be one of safest, most common medical procedures performed in the nation.[33] As the National Academies summarizes: "Today, the available scientific evidence on abortion's health effects is quite robust,"[34] and "the

[32] *See* Upadhyay et al. (2018); Elizabeth G. Raymond et al., *Mortality of Induced Abortion, Other Outpatient Surgical Procedures and Common Activities in the United States*, 90 Contraception 476, 477 (2014) (abortion is as safe or safer than many other commonly performed outpatient procedures); *see also* ACOG, *Practice Bulletin No. 143: Medical Management of First-Trimester Abortion* (Mar. 2014, reaff'd 2016), https://www.acog.org/-/media/project/acog/acogorg/clinical/files/practice-bulletin/articles/2014/03/medical-management-of-first-trimester-abortion.pdf; ACOG, Practice *Bulletin No. 135:Second-Trimester Abortion* (June 2013, reaff'd 2019); Kelly Cleland et al., *Significant Adverse Events and Outcomes after Medical Abortion*, 121 Obstet. & Gynecol. 166, 166 (2013); *see also* Nat'l Acads. at 74-75.

[33] Nat'l Acads. at 37 & 77-78; *see also id*. at 162-63.

[34] *Id*. at 17.

extensive body of research documenting the safety of abortion care in the United States reflects the outcomes of abortions provided by thousands of individual clinicians."[35]

63. Second, when Dr. Harrison and Dr. Valley discuss complications of abortion, they do so without acknowledging that those complications are exceedingly rare. As the National Academies summarizes: "The clinical evidence makes clear that legal abortions in the United States—whether by medication, aspiration, D&E, or induction—are safe and effective."[36] Serious complications are exceedingly rare; "in the vast majority of studies, they occur in fewer than 1 percent of abortions."[37] According to one reliable study, as to first-trimester aspiration abortion procedures, the rate of serious complications (defined as requiring hospital admission, surgery, or blood transfusion) was 0.16%, and the rate of serious complications for second-trimester procedure or later procedures was 0.41%.[38] The hospital-admission rate for all women was 0.02%.[39]

64. Third, to the extent Drs. Harrison, Valley, and Sanders discuss complications, they discuss all or minor complications, which sweeps in incidents that may require further medical treatment but no visit to the hospital.[40] In addition to being rare, almost all of the complications associated with medication abortion, or with abortion procedures especially prior to 22 weeks LMP, can be safely and appropriately managed in an outpatient, clinic setting—i.e., do not require hospitalization.[41] For example, most cases of hemorrhage are managed in the clinic setting with uterotonics, medications that cause uterine contractions and reduce bleeding.[42] Likewise, most

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[35] *Id.* at 14.
[36] *Id.* at 10-11.
[37] *Id.* at 77-78.
[38] Upadhyay et al. (2015).
[39] *Id.*
[40] *See, e.g.*, Valley Decl. ¶¶ 3–5, ECF No. 54-4; Harrison Decl. ¶¶ 10, 12, 17–18, 26–27, ECF No. 54-7; Sanders Decl. ¶ 8, ECF No. 54-8.
[41] *See* Sarah C. M. Roberts et al., *Association of Facility Type with Procedural-Related Morbidities and Adverse Events Among Patients Undergoing Induced Abortions*, 319(24) JAMA 2497, 2503–04 (2018); Nat'l Acads. at 14.
[42] Jennifer Kearns & Jody Steinhauer, *Management of Postabortion Hemorrhage*, 87 Contraception 331, 333 (2013).

cases of cervical laceration are managed in the clinic setting either with cauterizing medications or by suturing the laceration.[43] And cases of incomplete abortion are generally managed in the clinic through repeat aspiration and medications.

65. Emergency room visits at which treatment is provided following an abortion are also rare. For example, the Upadhyay (2015) study about ER visits following abortion found only 0.87% of all abortions resulted in an emergency department visit at which treatment was provided for an abortion-related condition.[44] While Dr. Harrison criticizes this study, it is notable because of its large sample size, which helps in estimating rare events. It is also noteworthy because follow-up at 6-weeks was likely to be essentially complete, particularly for complications that were diagnosed or treated outside the facility at which the abortion was provided.

66. Complications such as hemorrhage, infection, and injury to other organs are also all far more likely to occur with a full-term pregnancy than with an abortion.[45] This is not surprising considering pregnancies ending in abortion are substantially shorter than those ending in childbirth and thus entail less time for pregnancy-related problems to occur or progress.[46] Certain dangerous pregnancy-related complications such as pregnancy-induced hypertension and placental abnormalities manifest themselves in late pregnancy; early abortion avoids these hazards.[47]

67. Finally, as to medication abortion, Dr. Harrison's declaration misrepresents the FDA Mifeprex label to suggest that medication abortion is unsafe. For instance, Dr. Harrison's declaration states that 85% of medication abortion patients report serious adverse reactions to mifepristone.[48] The FDA label plainly states that serious adverse reactions, which include

[43] *Id.*
[44] Upadhyay et al. (2015) at 177.
[45] Elizabeth G. Raymond et al., *Comparative Safety of Legal Induced Abortion & Childbirth in the United States*, 119(2) Obstet. & Gynecol. 215, 216–17 (2012).
[46] *Id.* at 217.
[47] *Id.*
[48] *See* Harrison Decl. ¶¶ 10-11, ECF No. 54-7.

transfusion, infections, and hemorrhage, occur in less than 0.5% of women.[49] The label also references common "adverse reactions"—meaning they occur in more than 15% of women, and which the label alternately refers to as side effects—including "nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness."[50] These side effects do not suggest mifepristone is unsafe; rather, as with other medications, patients are advised of the side effects and counseled as to how to address them.[51]

68. Dr. Harrison's declaration also takes a partial quote from the "black box warning" on the Mifeprex label to suggest that serous and fatal infection and bleeding are common adverse reactions to mifepristone use. Dr. Harrison's declaration quotes the label as stating: "Warning: Serious and Sometime Fatal Infections or Bleeding."[52] The full label, however, states: "Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following MIFEPREX use. No causal relationship between the use of MIFEPREX and misoprostol and these events has been established."[53] By only partially quoting from the label, Dr. Harrison gives a misimpression about how rare these reactions are and their causal relationship to mifepristone. As the National Academies' comprehensive review of medical literature confirms, medication abortion is extremely safe.[54]

69. Also contrary to Dr. Harrison's suggestion,[55] the fact that Mifeprex has a Risk Evaluation and Mitigation Strategy (REMS) does not undermine this well-documented safety record.[56] Moreover, as ACOG has stated: the REMS "requirements are inconsistent with those for

[49] Mifeprex Label at 7-8.
[50] *Id.*
[51] Mifeprex Label at 16.
[52] Harrison Decl. ¶ 11, ECF No. 54-7.
[53] Mifeprex Label at 2.
[54] Nat'l Acads. at 55–56.
[55] Harrison Decl. ¶ 11, ECF No. 54-7.
[56] Nat'l Acads. at 55–56.

other medications with similar or greater risks . . . and serve as barriers to access without supporting demonstrated improvements to patient safety or outcomes."[57] In fact, "[e]vidence regarding the safety of mifepristone for medication-induced abortion, used by over 3 million women in the U.S. since FDA approval in 2000, supports the removal of the REMS."[58]

I declare under penalty of perjury the foregoing is true and correct.

Mark Nichols M.D.

Executed April 10, 2020

[57] ACOG, *Improving Access to Mifepristone for Reproductive Health Indications: Position Statement* (June 2018), https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/improving-access-to-mifepristone-for-reproductive-health-indications.
[58] *Id.*

Exhibit 1-1

CURRICULUM VITAE
OREGON HEALTH & SCIENCE UNIVERSITY

NAME	**Mark D. Nichols, MD**	**DATE**	February 2020April 9, 2020
Academic Rank:	**Professor**		
Department/Division:	**Obstetrics and Gynecology**		
Professional Address:	**3181 SW Sam Jackson Park Road - UHN 50**		
E-Mail Address:	**nicholsm@ohsu.edu**		

I. EDUCATION

Undergraduate and Graduate (Include Year, Degree, and Institution):

1975 Bachelor of Science in Biological Sciences, University of California, Davis

Postgraduate (Include Year, Degree, and Institution):

1979 Doctor of Medicine, University of California, Davis
1979-1983 Internship and Residency
Department of Obstetrics and Gynecology
Oregon Health Sciences University
1990 Research Fellow
Margaret Pyke Center, Middlesex Hospital
University College, London, England
(January - July)
July, 1996 Advanced Cardiac Life Support Provider Course
American Heart Association
Portland OR (Recertified in biannually, last in April, 2016)

Certification (Include Board, Number, Date, and Recertification):

American Board of Obstetrics and Gynecology, December 1985
Elected Fellow American College of Obstetrics and Gynecology, September 1986

Licenses (Include State, Date, Status, Number, and Renewal Date):

April 11, 1981 State of Oregon, License No. 12638, biannually renewed,
Sept. 2010 Zambia, Temporary Medical License
March 2020 State of Montana, License No. 85802

II. PROFESSIONAL EXPERIENCE

Academic (Include Year, Position, and Institution):

1983 - 1993 Assistant Professor, Oregon Health Sciences University
1993 - 2003 Associate Professor, Oregon Health & Science University
2003 – present Professor, Oregon Health & Science University

Administrative (Include Year, Position, and Institution):

1983 - 1995 Assistant Director, Residency Training Program, Oregon Health Sciences University, Department of Obstetrics and Gynecology
1988 - 2013 Chief, Division of General Gynecology and Obstetrics, Department of Obstetrics and Gynecology, Oregon Health & Science University, Portland OR

2001 - 2010	Director, Family Planning Fellowship, Oregon Health & Science University, Portland OR
2010 - 2013	Co- Director, Family Planning Fellowship, Oregon Health & Science University, Portland OR
2013 – present	Director Emeritus, Family Planning Fellowship, Oregon Health & Science University, Portland OR

Other (Include Year, Position, and Institution):

1994	Interim Medical Director, Planned Parenthood Columbia Willamette Affiliate
1994 - 2011	Medical Director, Planned Parenthood Columbia Willamette Affiliate
2011 - 2013	Co-Medical Director, Planned Parenthood Columbia Willamette Affiliate
1997 - 2001	Family Planning Consultant, Oregon Health Division

International Work

2010	Consultant, Population Services International, Zambia
2010	Member, Surgical Team mission to Gimbie Hospital, Ethiopia
2012	Consultant, Population Services International, Nigeria
2014	Consultant, Population Services International, Tanzania
2014	Visiting Professor, Mekelle University, Ethiopia
2015	Obstetrician, Medecins Sans Frontieres, South Sudan
2015	Consultant, Laos Nutrition Institute, Vientiane, Laos
2016	Visiting Professor, Mekelle University, Ethiopia
2017	Obstetrician, Medecins Sans Frontieres, South Sudan
2018	Consultant, Population Services International, Vietnam

III. SCHOLARSHIP

Area(s) of Research/Scholarly Interest:

Family planning with particular interest in surgical and medical abortion, emergency contraception, hormonal contraception, and training fellows, residents and medical students in family planning.

Grants and Contracts:

1. R W Johnson Pharmaceutical, "A Double Blind Placebo Controlled Safety and Efficacy Study of Antocin™ for the Prolongation of Gestation," November 1994 - July 1997, $138,654. PI: Jeff Jensen, MD, Sub PI: Mark Nichols, MD

2. The Population Council, Inc., RU-486, "Evaluation of the Efficacy, Safety and Acceptability of Mifepristone and Misoprostol in Inducing Abortion in Pregnant Women with Amenorrhea of up to 63 Days," November 1994 - December 1995 - $209,800. PI: Mark Nichols, MD

3. Wyeth-Ayerst Laboratories and University Hospital Consortium, "Norplant Observational Cohort," June 1995 - June 2003, $275,000. PI: Mark Nichols, MD

4. Wyeth-Ayerst Laboratories, "A Multi center, Open-Label, Randomized, Comparative Study to Evaluate the Effects of Alesse™ and Loestrin FE 1/20® on Clinical and Biomedical Measures of Androgenicity," November 1996 - June 1997, $16,920. PI: Mark Nichols, MD

5. Parke-Davis, "A Randomized, Double Blind, Active-Controlled, Parallel Group, Multi-center Study Assessing Menstrual Cycle Control and Ovulation Suppression Associated with Vaginal Administration of Five Dose Combinations of Norethindrone Acetate and Ethinyl Estradiol," December 1996 - March 1997, $86,689. PI: Leon Speroff, MD, Sub PI: Mark Nichols, MD

6. Pharmacia & Upjohn, "Cyclo Provera™ Contraceptive Injection: A Comparative Study of Safety, Patient Acceptability and Efficacy to Ortho-Novum® 7/7/7, 28 Tablets," June 1997 - June 1999, $92,556. PI: Mark Nichols

7. Organon, "An Open Label, Multi center, Randomized, Comparative Safety, Efficacy, Cycle Control, and Quality of Life Study of CTR 25, Alesse™, and Ortho Tri-Cyclen®," April 1998 - July 1999, $76,310. PI: Kenneth Burry, MD, Sub PI: Mark Nichols, MD

8. John Hopkins University, "Comparing Acceptability of Manual vs Electrical Vacuum Aspiration for First Trimester Induced Abortion," $37,310. June 2000 – July 2001. PI: Mark Nichols, MD

9. Pharmacia Co. "Phase III Study of DMPA Injection (DMPA-SC) in Women with Endometriosis in the US and Canada" $42,480. January 2000 - January 2001. PI: Mark Nichols

10. Galen Holdings "A Multi-center, Randomized Controlled Double-Blind Study to Determine Efficacy in the Relief of Hot Flushes in Women Receiving Oral Estradiol" $23,527. Sept. 2001 – Aug. 2002. PI: Leon Speroff, MD, Sub-PI: Mark Nichols, MD

11. Organon-Thebes "A Multinational, Multi-center, Randomized Controlled Trial, to Assess the Endometrial Histological Profile Following Treatment with Tibolone (ORG 0D14) Versus Conjugated Estrogen (CE) Plus Medroxyprogesterone Acetate (MPA) in Postmenopausal Women" $138,000. PI: Jeffrey Jensen, MD, Sub PI: Mark Nichols, MD

12. Pfizer Care "A Randomized, Double Blind, Multi-Center, 24 Week Study to Assess Cumulative Amenorrhea in Postmenopausal Women Taking Femhrt® and Prempro®". $37,275. PI: Leon Speroff, MD, Sub-PI: Mark Nichols, MD

13. Buffett Foundation Grant. "Intrauterine Lidocaine Infusion for Pain Management in First Trimester Abortions" $48,000. June 2002 – June 2003 PI: Alison Edelman, MD Sub PI: Mark Nichols, MD

14. Buffett Foundation Grant. "Continuous Oral Contraceptive Pills: Are Bleeding Patterns Dependent on the Hormone Chosen?" $51,000. PI: Alison Edelman, MD Sub PI: Mark Nichols, MD

Publications/Creative Work:

Peer-reviewed

1. Nichols, M. Diagnosing Breast Disease, *West. J. Med*., 148:324, 1988.

2. Novy MJ, Haymond J, Nichols M. Shirodkar Cerclage in a Multifactorial Approach to the Patient with Advanced Cervical Changes, *AJOG*, 162:1412-20, 1990.

3. Nichols MD. Review of Vulvar Ulcers, *Postgraduate Obstet. Gynecol.*, 11(No. 7):1991.

4. Nichols M, Robinson GER, Bounds W, Johnson J, Upward E, Newman B, Guillebaud J. Effect of Four Combined Oral Contraceptives on Blood Pressure in the Pill-Free Interval, *Contraception*, 47:367-76, 1993.

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Birth After Maternal Fontan Repair: Report of Two Cases, *Anesth Analg*, 78:1190-2, 1994.

7. Nichols M. Curriculum Change in an OB/GYN Residency Program and It's Impact on Pregnancy in Residency, *AJOG*, 170:1658-65, 1994.

8. Winikoff B, Ellertson C, Elul B, Sivin I; for the Mifepristone Clinical Trials Group. Acceptability and Feasibility of Early Pregnancy Termination by Mifepristone-Misoprostol. Results of Large Multi center Trial in the United States, *Arch Fam Med*, 7:360-6, 1998. (Member of the Mifepristone Clinical Trials Group)

9. Spitz IM, Bardin CW, Benton L, Robbins A. Early Pregnancy Termination with Mifepristone and Misoprostol in the United States, *New Eng J Med*, 338:1241-7, 1998. (Cited as Principal Investigator)

10. Jensen JT, Astley SJ, Morgan E, Nichols MD. Outcomes of Suction Curettage and Mifepristone Abortion in the United States, *Contraception*, 59(3):153-9, 1999.

11. Kaunitz AM, Garceau RJ, Cormie MA, Lunelle Study Group (Member). Comparative Safety, Efficacy and Cycle Control of LUNELLE Monthly Contraceptive Injection (Medroxyprogesterone Acetate and Estradiol Cypionate Injectable Suspension) and Ortho-Novum 7/7/7 Oral Contraceptive (Norethindrone/Ethinyl Estradiol Triphasic), *Contraception*, 60:179-187, 1999.

12. Thorneycroft IH, Stanczyk FZ, Bradshaw KD, Ballagh SA, Nichols m, Weber ME. Effect of Low-dose Oral Contraceptives on Androgenic Markers and Acne, *Contraception*, 60:255-62, 1999.

13. Paul M, Schaff E, Nichols M. The Roles of Clinical Assessment, Human Chorionic Gonadotropin Assays, and Ultrasonography in Medical Abortion Practice, *Am J Obstet Gynecol,* 183(2):S34-S43, 2000.

14. Borgatta L, Burnhill M, Haskell S, Nichols M, Leonhardt K. Instituting Medical Abortion Services: Changes in Outcome and Acceptability Related to Provider Experience, *JAMWA*, 55:173-6, 2000.

15. Westhoff C, Dasmahapatra R, Winikoff B, Clarke S, and the Mifepristone Clinical Trials Group. Predictors of analgesia use during supervised medical abortion. *Contraception* 2000;61:225-229 (Member of the Mifepristone Clinical Trials Group)

16. Bird ST, Harvery SM, Nichols M. Comparing the Acceptability of Manual Vacuum Aspiration and Electric Vacuum Aspiration as Methods of Early Abortion. *JAMWA* 56: 124-126;2001

17. Edelman AT, Nichols MD, Jensen J. Comparison of pain and time of procedures with two first-trimester abortion techniques performed by residents and faculty *Am J Obstet Gynecol* 184:1564-7;2001

18. Nichols M, Edelman A. RU 486 for Primary Care Providers. *Primary Care Reports* , 7:89-95;2001

19. Phair N, Jensen J, Nichols M. Paracervical block and elective abortion: The effect of waiting between injection and procedure pain. *Am J. Obstet. Gynecol.* 186:1304-7;2002

20. Nichols M, Morgan E, Jensen J. Comparing bimanual pelvic examination to ultrasound measurements for the assessment of gestational age in the first trimester of pregnancy. *Journal Repro Med* 50:825-8;2002

21. Kwiecien M, Edelman A, Nichols MD, Jensen JT. Bleeding patterns and patient acceptability of standard or continuous dosing regimens of a low dose oral contraceptive: a randomized trial. *Contraception* 67:9-13;2003

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survey of National Abortion Federation providers. *Contraception* 67:49-51;2003

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29. Rodriguez M, Nichols M Adventitious Bursitis: An Unusual Cause of a Vulvar Mass. Accepted for publication in *Journal of Reproductive Medicine*

30. Cwiak CA, Edelman AB, Hatcher RA, Zieman M, Nichols MD, Jensen JT, Emmons SL, and Khan IM. Teaching contraception: An interactive presentation using *Managing Contraception. AJOG* 191:1788-92;2004

31. Harvey S M, Nichols MD. Development and Evaluation of the Abortion Attributes Questionnaire. *Journal of Social Issues*. 61:95-107;2005

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34. Emmons SL. Nichols M. Schulkin J. James KE. Cain JM. The influence of physician gender on practice satisfaction among obstetrician gynecologists. *American Journal of Obstetrics & Gynecology.* 194:1728-38; 2006

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42. Munks EB, Edelman AB, Jensen JT, Nichols MD, Burry K and Patton P. IVF Patients' Attitudes Toward Multifetal Pregnancy Reduction. *Journal of Repro Med* 52:635;2007

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49. Kraemer DF, Yend, P, Nichols, M. An economic comparison of female sterilization of hysteroscopic tubal occlusion with laparoscopic bilateral tubal ligation. *Contraception* 80: 254–260, 2009

50. Renner RM. Jensen JT. Nichols MD. Edelman A. Pain control in first trimester surgical abortion.*Cochrane Database of Systematic Reviews.* (2):CD006712, 2009.

51. Kaneshiro B, Jensen JT, Carlson N, Nichols M, Edelman A. Treatment of Unscheduled Bleeding in Continuous Oral Contraceptive Users With Doxycycline: A Randomized Controlled Trial. *Obstet Gynecol.* 115(6):1141-9, 2010 Jun

52. Renner RM. Jensen JT. Nichols MD. Edelman AB Pain control in first-trimester surgical abortion: a systematic review of randomized controlled trials. *Contraception*. 81(5):372-88, 2010 May.

53. Isley M, Edelman A,. Kaneshiro B,. Peters,D. Nichols, M, Jensen, JT. Sex education and contraceptive use at coital debut in the United States: results from Cycle 6 of the National Survey of Family Growth. *Contraception*. 82(3):236-42, 2010 Sep

54. Kaneshiro B, **Bednarek P,** Isley M, **Jensen J, Nichols M, Edelman A**. Blood loss at the time of first-trimester surgical abortion in anticoagulated women. Contraception 2011; 83:431-435.

55. Renner RM, **Nichols M, Jensen JT,** Hong L**, Edelman AB**. Paracervical block for pain control in first-trimester surgical abortion: a randomized controlled trial. Obstet Gynecol 2012; 119: 1030-1037.

56. Kaneshiro B**, Edelman AB,** Carlson N**, Nichols M, Jensen JT**. A randomized controlled trial of subantimicrobial doxycycline to prevent unscheduled bleeding with continuous oral contraceptive pill use. Contraception.2012; 85: 351-358.

57. Isley MM, **Jensen JT, Nichols MD,** Lehman A**, Bednarek P, Edelman A**. Intrauterine lidocaine infusion for pain management during outpatient transcervical tubal sterilization: a randomized controlled trial. Contraception 2012; 85: 275-281.

58. Kaneshiro B, **Edelman A,** Carlson N**, Nichols M, Jensen J**. Unscheduled bleeding with continuous oral contraceptive pills: a comparison of progestin dose. *Contraception accepted 2011, available epub*

59. Bayer LL; Jensen JT; Li H; **Nichols MD**; Bednarek PH. Adolescent experience with intrauterine device insertion and use: a retrospective cohort study. *Contraception. 86(5):443-51, 2012 Nov.*

60. Micks EA; Edelman AB; Renner RM; Fu R; Lambert WE; Bednarek PH; Nichols MD; Beckley EH; Jensen JT. Hydrocodone–Acetaminophen for Pain Control in First-Trimester Surgical Abortion: A Randomized Controlled Trial. O*bstetrics & Gynecology. 120(5):1060-9, 2012 Nov.*

61. Goldthwaite LM; Baldwin MK; Page J; Micks EA; **Nichols MD**; Edelman AB; Bednarek PH.Comparison of interventions for pain control with tenaculum placement: a randomized clinical trial. *Contraception. 89(3):229-33, 2014 Mar.*

62. Krashin JW; Edelman AB; **Nichols MD**; Allen AJ; Caughey AB; Rodriguez MI. Prohibiting consent: what are the costs of denying permanent contraception concurrent with abortion care?. *American Journal of Obstetrics & Gynecology. 211(1):76.e1-76.e10, 2014 Jul.*

63. Bayer LL; Edelman AB; Fu R; Lambert WE; **Nichols MD**; Bednarek PH; Miller K; Jensen JT. An Evaluation of Oral Midazolam for Anxiety and Pain in First-Trimester Surgical Abortion: A Randomized Controlled Trial.*Obstetrics & Gynecology. 126(1):37-46, 2015 Jul.*

64. Micks E, Edelman A, Botha R, Bednarek P, **Nichols M**, Jensen J. The effect of sevoflurane on interventions for blood loss during dilation and evacuation procedures at 18–24 weeks of gestation: a randomized controlled trial. Contraception 91 (2015) 488–494

65. Baldwin MK, Edelman AB, Lim JY, **Nichols MD**, Bednarek, PH,, Jensen JT. Intrauterine device placement at 3 versus 6 weeks postpartum: a randomized trial. *Contraception 93 (2016) 356–363*

66. Renner R-M, Edelman AB, **Nichols MD**, Jensen JT, Lim JY, Bednarek PH Refining paracervical block techniques for pain control in first trimester surgical abortion: a randomized controlled noninferiority trial. *Contraception 94 (2016) 461–466*

67. Patil E, Darney B, Orme-Evans K, Beckley E, Bergander L, **Nichols M**, Bednarek PH. Aspiration Abortion With Immediate Intrauterine Device Insertion: Comparing Outcomes of Advanced Practice Clinicians and Physicians. *Journal of Midwifery & Women's Health. 61(3):325-330, March 2016*

68. Bayer LL, Edelman AB, Fu R, Lambert WE, **Nichols MD**, Bednarek PH, Miller K, Jensen JT. An Evaluation of Oral Midazolam for Anxiety and Pain in First-Trimester Surgical Abortion. A Randomized Controlled Trial. *Obstet Gynecol 2015;126:37–46*

Non-peer-reviewed

1. Nichols MD. Formal Discussant. An Obstetric and Gynecologic Clerkship's Influence on a Medical Community, *Am J Obstet Gynecol*, 176:1363-8, 1997.

2. Nichols, MD. Formal Discussant. Real-time Ultrasonographically Guided Removal of Nonpalpable and Intramuscular Norplant Capsules, *Am J Obstet Gynecol*, 178:1185-93, 1998.

3. Nichols, MD. Formal Discussant. Cytologic evaluation of non-bloody breast cyst fluid. *Am J Obstet Gynecol, Am J Obstet Gynecol*, 182:1300-5, 2000

4. Nichols, MD. Letter to the Editor, "Fewer Abortions would be needed". *Oregonian*, June 15, 2001

5. Nichols, MD. Methotrexate for management of a pregnancy in a non-communicating uterine horn. Letter to the editor. *Journal Repro Med* 50:878-9;2002

6. Nichols, MD. Clinical Trials Report, *Current Women's Health Reports*, 2:407-408;2002

7. Reeves MF; Blumenthal PD; Jones RK; **Nichols MD**; Saporta VA. New research at the 2014 National Abortion Federation Annual Meeting: continuously improving abortion care. *Contraception. 89(5):339-40, 2014 May.*

8. Reeves MF; Blumenthal PD; Jones RK; **Nichols MD**; Saporta VA. New research at the 2015 National Abortion Federation Annual Meeting: putting research into practice.*Contraception. 91(5):359, 2015 May.*

9. Darney P; Creinin MD; **Nichols M;** Gilliam M; Westhoff CL; Tenth anniversary of the Society for Family Planning. *Contraception. 92(4):279-81, 2015 Oct.*

Publications (submitted)

Chapters

1. Nichols M. "Faculty Ownership". In: *Teaching and Evaluating Clinical Skills*, 1995, APGO.

2. Nichols M, Halvorson-Boyd G, Goldstein R, Gevirtz D and Healow D. "Pain Management" in *Management of Unintended and Abnormal Pregnancy.* Wiley –Blackwell, 2009

Abstracts

1. Thulin PC, Carter JH, Nichols MD, Kurth M, Nutt JG. Menstrual-cycle Related Changes in Parkinson's Disease, *Neurology*, 46:A376, 1996.

2. Fossum GT, Thomas M, Wise R, Nichols M, Sinofsky F, Pasquale S. Preliminary Evaluation of a New Instrument Design for the Removal of Norplant Capsules.

3. Bird ST, Harvey SM, Nichols MD. Women's Acceptability of Manual Vacuum Aspiration (MVA: An Exploratory Study of Abortion Patients in Portland, Oregon.

4. Romm J, Nichols M. The Men's Group: Discussion Group for Male OB/GYN Residents, International Society of Psychosomatic Obstetrics and Gynecology, June 1998, Washington DC.

5. Stanczyk FZ, Bradshaw KD, Ballagh BA, Nichols MD, Thorneycroft, LH. Effect of Oral Contraceptive Progestins on Production of Ovarian, Adrenal and Peripheral Androgens, European Society of Contraception, June 1998, Prague.

6. Sheryl Thornbird PhD, Marie Harvey DrPH, Linda Beckman,PhD, Mark Nichols, MD, Paul Blumenthal. MD. Men's involvement in abortion: Perceptions of women having abortions in three U.S. cities Population, Family Planning, and Reproductive Health section of the 130th Annual APHA Meeting, Philadelphia, PA November, 2002.

7. Singh RH, Nichols MD, Rogers K, Ghanem KG, & Blumenthal Pd. Subjective predictors of pain in women undergoing electrical vacuum aspiration (eva) versus manual vacuum aspiration (mva) for first trimester abortion. Assoc. of Reproductive Health Professionals Annual meeting, Tampa FL, Sept. 2005

8. Edelman A, Nichols M, Leclair C, & Jensen JT. 4% intrauterine lidocaine infusion for pain management in first trimester abortions. Assoc. of Reproductive Health Professionals Annual meeting, Tampa FL, Sept. 2005.

9. Drath E, Nichols M, & Edelman A. Ultrasound, Twin Gestation, and Abortion Decision Making: Patients and Providers. NASPOG Annual Scientific Meeting, February, 2006, Hawaii

10. Bednarek P, Nichols M, Edelman A, Jensen JT, Truitt S, Creinin MD. Effect of observed start compared with Sunday start on contraceptive continuation after medical abortion. *Obstet Gynecol* 2007, supp 57S.

<u>Audio Presentations</u>

1. "RU-486," Audio-Digest Obstetrics and Gynecology, Vol. 41, No. 8, April 19, 1994

2. "Family Planning/STD Case Consultation," Center for Health Training, June 7, 1999

3. "Legal and Medical Implications of the Federal Abortion Ban" Podcast from Lewis & Clark Law School, Portland, OR Jan. 2006

<u>Posters</u>

1. Nichols MD, Kirk EP. Resident Retreat: A Stress Reducer and Morale Booster, CREOG and APGO Meeting, March 1991, Orlando, FL

2. Thomas L, Nichols MD. Ultrasound Evaluation of the Post Mifepristone Abortion Patient, Pacific Coast Obstetrical and Gynecological Society, Sunriver OR, 1996

3. Edelman A, Nichols MD. Comparison of Resident and Faculty Performed Abortions using Two Different Abortion Techniques, District VIII Meeting, American College of Obstetricians and Gynecologists, Anchorage AK, August 2000

4. Edelman A, Nichols MD. Comparison of Resident and Faculty Performed Abortions using Two Different Abortion Techniques, District VIII Meeting, American College of Obstetricians and Gynecologists, Anchorage AK, August 2000.

5. Phair N, Jensen J, Nichols M. Paracervical block and elective abortion: The effect of waiting between injection and procedure pain, PCOGS Annual meeting, Ashland OR, October, 2001. Received award as best poster of the meeting.

6. Lew R, Edelman A, Cwiak C, Jensen J, Nichols M. Acceptability of Contraceptive-Induced Amenorrhea in American Women, ACOG Annual Clinical Meeting, San Francisco, May 2005.

7. Koontz, Edelman A, Jensen J, Nichols M. Continuous Oral Contraceptives: Are Bleeding Patterns Dependent on the Hormones Given? ACOG Annual Clinical Meeting, San Francisco, May 2005.

8. Paula Bednarek, MD, Mark Nichols, MD, Alison Edelman, MD, MPH, Jeffrey T. Jensen, MD, MPH, Sarah Truitt, MD, Mitchell D. Creinin, MD. Effect of "Observed Start" versus "Sunday Start" on hormonal contraception continuation after medical abortion. ACOG Annual Clinical Meeting, SanDiego, May 2007

Invited Lectures, Conference Presentations or Professorships (since promotion to Associate Professor):

Local (Selected)

1. "IUD Review," Grand Rounds, Kaiser Sunnyside Hospital, Department of Obstetrics and Gynecology, January 1993.

2. "Breast Disease for the Gynecologist," Langley Memorial Lectures, Portland OR, February 1993.

3. "Second Trimester Abortion Technique," Grand Rounds, Bess Kaiser Hospital, Obstetrics and Gynecology Department, April 1993.

4. "RU-486," City Club of Portland, July 1994.

5. "Circumcision Review," Grand Rounds, OHSU, Department of Obstetrics and Gynecology, June 1995.

6. "Abortion" and "Breast Disease," OHSU, Nursing School Advanced Gynecology Course, October 1995.

7. "Emergency Management of Vaginal Bleeding," St. Vincent Hospital, January 1996.

8. "Trauma in Pregnancy," OHSU, Emergency Medicine Residents, September 1996.

9. "Contraception Review," OHSU, Internal Medicine Residents, January 1997.

10. "Management of Miscarriages," OHSU, Student Health Service, January 1997.

11. "Contraception and World Population," Portland State University Population Control Class, January 1997.

12. "Emergency contraception: Coca-Cola to Mifepristone," Grand Rounds, OHSU, Department of Obstetrics and

Gynecology, April 1997.

13. “First Trimester Bleeding,” OHSU, Emergency Medicine Residents, June 1997.

14. “Approach to Dysfunctional Uterine Bleeding,” Grand Rounds, OHSU, Internal Medicine Department, March 1998.

15. “Medical Abortion Review,” Kaiser Grand Rounds, Clackamas OR, December 1998.

16. “Update on Emergency Contraception and Medical Abortion,” Grand Rounds, OHSU, Department of Obstetrics and Gynecology, January 1999.

17. “Emergency Contraception,” OHSU, School of Nursing, Graduate Program, January 1999.

18. “Emergency Contraception,” Planned Parenthood, Columbia/Willamette Affiliate, Portland OR, March 1999.

19. “Emergency Contraception,” Mt. Hood Medical Center, OB/GYN and Pediatrics Department Meeting, June 1999.

20. “Abnormal Uterine Bleeding,” Grand Rounds, OHSU, Department of Obstetrics and Gynecology, July 1999.

21. “Medical Abortion Review,” St. Vincent Medical Center Ob/Gyn Dept., Portland OR, October 1999.

22. Norplant/IUD Training, Clinicians from Lane, Linn, Josephine, Tillamook, Marion, Coos, Polk, Lincoln, Malheur, Douglas, Washington, Multnomah and Klamath Counties and Planned Parenthood, Portland OR, November 1999.

23. “Review of Emergency Contraception,” Tuality Hospital, Hillsboro OR, March 2000.

24. “Wedge Issues of Choice,” NARAL Leadership Training, Unitarian Church, Portland OR, April 2000.

25. “Emergency Contraception” Emanuel Hospital, Ob/Gyn Department, June 2000

26. “Emergency Contraception” Center for Women’s Health, OHSU, September 2000

27. “Mifepristone: FDA Approval and Review,” OHSU, Grand Rounds, Department of Obstetrics and Gynecology, October 2000.

28. “RU486," OB/GYN Department Educational Conference, Providence St. Vincent Medical Center, Portland OR, March 2001.

29. “Review of Emergency Contraception”. Pediatric Department, Emanuel Hospital, Portland, OR, February, 2002

30. “Contraceptive Update: What’s New?” OHSU, Grand Rounds, Department of Obstetrics and Gynecology, March 2002.

31. “Women seeking abortion care. Are they discriminated against?” Reed College VOX course, Portland, OR, March, 2002.

32. “Update in Contraception” Lorenzen Women’s Physician Forum, Portland, OR, November 2002

33. "Update in Contraception" Grand Rounds, Good Samaritan Hospital, Portland, OR, February 2003

34. "Becoming an abortion provider" Reed Vox seminar, Reed College, Portland, OR, April, 2003

35. "Planned Parenthood Update" SW Washington Medical Center, Ob/Gyn Department Grand Rounds, Vancouver, WA, June, 2003

36. "Update on Contraception", Student Health Center, OHSU, November 2003

37. "IUD Review", Legacy Hospital CNM Department, Portland, OR February 2004

38. "Oral Contraceptive Update", St. Vincent Medical Center, Resident teaching conference, Portland, OR, March 2004

39. "Essure device for female sterilization", SW Washington Med. Center, Ob/Gyn dept. Grand Rounds, Vancouver, WA, Jan. 2005

40. "Transcervical Female Sterilization", East Portland Rotary Club, Portland, OR Jan. 2005

41. "Legal and Medical Implications of the Federal Abortion Ban" Lewis & Clark Law School, Portland, OR Jan. 2006

42. "Pain Management of Gyncologic Procedures" Grand Rounds, OHSU Ob/Gyn department, Portland, OR Oct. 2008

43. "Management of Breech Presentation" Grand Rounds, OHSU Ob/Gyn department, Portland, OR Sept 2009

44. "Alternatives to Hysterectomy" Brown Bag Lecture, OHSU, Portland, OR October 2009

45. "Pain management for gynecologic procedures", Grand Rounds Dept of Anesthesiology, OHSU, September 2010.

<u>Regional</u>

1. "Norplant Review and Insertion Training," Washington Academy of Family Practice Review Course, Spokane WA, April 1993.

2. "Gynecology for the Primary Care Provider: Preventive Health Care," Primary Care Conference, Sunriver OR, June 1993.

3. "Contraception for Patients with Chronic Health Problems," Nurse Practitioners of Oregon, September 1995.

4. "RU-486 Review," Ashbury Memorial Lectureship, Guest Speaker, Corvallis OR, November 1995.

5. "Common Gynecologic Problems and the Internist," 3rd Annual Internal Medicine Review Course, April 1996.

6. "Contraceptive Update," Family Planning Conference, Eugene OR, September 1996.

7. "Gynecological Procedures," 28th Annual Family Practice Review, Portland OR, February 1997.

8. "Contraception," 28th Annual Family Practice Review, Portland OR, February 1997.

9. "Family Planning," Reproductive Health Conference 1997, Portland OR, March 1997.

10. "Elective Abortions: RU-486 and Methotrexate," Reproductive Health Conference, Portland OR, March 1997.

11. "Medical Abortion," 5th Annual Oregon Section ACOG Update in Obstetrics, Gynecology, and Primary Care, Bend OR, April 1997.

12. "Hormonal Contraception for Females: Recommendations and Guidelines," Endocrine Conference, Ashland OR, August 1997.

13. "Emergency Contraception: From Coca-Cola to Mifepristone," 21st Annual Pacific NW Review of OB-GYN, Portland OR, October 1997.

14. "Office Gynecology," 29th Annual Family Practice Review, Portland OR, February 1998.

15. "IUD Insertion Technique," Roseburg OR, March 1998.

16. "Office Gynecology," 5th Annual Internal Medicine Review, Portland, April 1998.

17. "Contraceptive Overview," Planned Parenthood, Eugene OR, November 1998.

18. "Emergency Contraception," 30th Annual Family Practice Review, Portland OR, February 1999.

19. "Gynecologic Procedures," 30th Annual Family Practice Review, Portland OR, February 1999.

20. "Emergency Contraception," Oregon Section, ACOG 6th Annual Meeting, Sunriver OR, April 1999.

21. "Emergency Contraception: New Innovations," Center for Health Training, 28th Annual Clinical Update, Portland OR, April 1999.

22. "Emergency Contraception," Sacred Heart Medical Center, 1st Annual Primary Care Conference, Eugene OR, May 1999.

23. "Update in Contraception," Sacred Heart Medical Center, 1st Annual Primary Care Conference, Eugene OR, May 1999.

24. " Laparoscopic Tubal Ligation Techniques," 23rd Annual Pacific NW Review of OB-GYN, Portland OR, October 1999.

25. "Impact of Religious Hospital Mergers on Training Residents in Abortion Care." Toward Rational Living Conference, Portland OR, November 1999.

26. "Gynecology: Office Procedures," 31st Annual Family Practice Review, Portland, February 2000.

27. "RU486 in OB/GYN," Women's Health Care Symposium, Eugene OR, September 2000.

28. "Savvy About Sex," Martha Browning Bryant Memorial Lecture, Oregon Chapter of The American College of Nurse-Midwives, October 2000.

29. "Emergency Contraception," Institute of Women's Health and Integrative Medicine, October 2000.

30. “Update on Pap Smears” Family Practice OB Ski and Women’s Health Conference, Bend OR, January 2001.

31. “Gynecological Skills Workshop”, Family Practice OB Ski and Women’s Health Conference, Bend OR, January 2001.

32. “Gynecology: Office Procedures,” 32nd Annual Family Practice Review, OHSU, February 2001.

33. “Dysfunctional Uterine Bleeding,” 8th Annual Internal Medicine Review, April 2001.

34. “Sonohysterography or SIS (Saline Infusion Sonography),” 8th Annual Oregon ACOG Update in Obstetrics and Gynecology, Bend OR, April 2001.

35. “Where are we with RU-486" Oregon Nurses Association/Nurse Practitioners of Oregon, 24th Annual Meeting, Eugene, OR Sept. 2001

36. “Pharmacology of Oral Contraceptives”, OHSU with 4 remote sites, Nurse Practitioner curriculum, Oct. 2001

37. “Laparoscopic Supracervical Hysterectomy: Making the Recovery Even Faster”. 25th Annual Pacific Northwest Review Conference, Portland OR, November 2001

38. “Review of Emergency Contraception”, Oregon Pharmacology Association, Nov. 2001

39. “Intrauterine contraception” Nurse Practitioner Training Course, Portland, OR, Jan. 2002

40. “What's new in contraception?” Montana section ACOG Annual Meeting, Big Sky, MT, Feb. 2002

41. “RU-486 in Ob/Gyn”, Montana section ACOG Annual Meeting, Big Sky, MT, Feb. 2002

42. “Review of Emergency Contraception”, Montana section ACOG Annual Meeting, Big Sky, MT, Feb. 2002

43. "What's New in Contraception", 33rd Annual Family Practice Review, Portland, February, 2002

44. "Gynecologic Procedures" 33rd Annual Family Practice Review, Portland, February, 2002

45. “Update on Contraception” Good Samaritan Hospital, Corvallis, OR, March 2002

46. “RU-486 in Ob/Gyn” Good Samaritan Hospital, Corvallis, OR, May, 2002

47. “Labor Inductions” OAFP Women’s Health Conference, Bend, OR, Jan. 2003

48. “The new IUD”OAFP Women’s Health Conference, Bend, OR, Jan. 2003

49. “Update in Contraception” Reproductive Health Conference, Portland, OR, March 2003

50. “IUD training” Reproductive Health Conference, Portland, OR, March 2003

51. “Essure Device for Tubal Sterilization” 10th Annual Oregon ACOG Update in Obstetrics and Gynecology, Bend OR, April 2003.

52. “Update on Contraception for the New Millenium” Women’s Health Care Symposium, Eugene, OR, May 2003

53. “Trans-Cervical Sterilization: A review of the Essure device” 27th Annual Pacific NW Review of OB-GYN, Portland OR, October 2003.

54. “Medical Abortion Review” National Abortion Federation Course, Portland, OR, October, 2003

55. "What's New in Contraception", 35th Annual Family Practice Review, Portland, February, 2004

56. "Gynecologic Procedures" 35th Annual Family Practice Review, Portland, February, 2004

57. “IUD Training” Center for Health Training, Portland, OR October, 2004

58. “Why Women Wait”. Western Regional meeting of Medical Students for Choice, Portland, October, 2004

59. “MVA Training Sessions” Western Regional meeting of Medical Students for Choice, Portland, October, 2004

60. “Ultrasound in Medical Abortion” Sponsored by NAF , Portland, OR, November, 2004

61. "Gynecologic Procedures" 36th Annual Family Practice Review, Portland, February, 2005

62. "Contraceptive Update" 36th Annual Family Practice Review, Portland, February, 2005

63. “Alternatives to Hysterectomy” 36th Annual Family Practice Review, Portland, February, 2005

64. “Looking in the Future: New Contraceptive Methods” Reproductive Health Conference, Portland, OR, March 2005

65. “Shortage of Abortion Providers in the U.S.” Students for Choice conference, Willamette University, Jan. 2006

66. "Gynecology Procedures" 37th Annual Family Practice Review, Portland, February, 2006

67. “Review of Medical Abortion” Pacific Northwest Review Course, Portland, OR October, 2006

68. “Implanon training” Sponsored by Implanon, Portland, OR March, 2007

69. “Review of Contraceptive Implants” Reproductive Health 2007, Portland, OR March 2007

70. “Management of Early Pregnancy Failure”, Nurse Practioners of Oregon annual meeting, Hood River, OR Oct. 2008

71. “Medical Abortion”, Nurse Practioners of Oregon annual meeting, Hood River, OR Oct. 2008

72. “ Addressing the abortion provider shortage” Western regional meeting, Medical Students for Choice, Portland, OR, April 2009

National

1. “IUD Review,” Grand Rounds, University of Maryland, Obstetrics and Gynecology Department, February 1993.

2. “IUD Review,” Grand Rounds, Pennsylvania Hospital, Obstetrics and Gynecology Department, May 1993.

3. “IUD Review,” Grand Rounds, Maricopa County, Obstetrics and Gynecology Department, June 1993.

4. “OB/GYN Review Course,” Loma Linda University, Guest Faculty, Yosemite CA, April 1995.

5. “Incorporating Abortion Training Into the Ob/Gyn Residency Curriculum,” National Abortion Federation Conference, Baltimore MD, November 1998

6. “Second Trimester Abortion Technique” and “Abortion Providers Panel: Incorporating Abortion Care Into Your Practice,” Medical Students for Choice, 6th Annual Meeting, Atlanta, GA, April 1999.

7. “Fine Needle Aspiration for the Evaluation of Breast Masses,” National Medical Committee Planned Parenthood Federation of America, Dallas TX, Sept. 1999.

8. “Parenteral Estrogen and Progestin Contraceptive: a Review,” Risk Management Seminar, National Abortion Federation, Denver CO, Sept. 1999.

9. “Faculty Models” National Abortion Federation Resident Training Workshop, New Orleans LA, February 2000.

10. “Building Support in Your Department & Negotiating the Contract: From a Residency Program Perspective,” National Abortion Federation Resident Training Workshop, New Orleans LA, February 2000.

11. “Background/Historical Context,” “Medications: Mifepristone, Misoprostol and Methotrexate,” “Protocol,” “Patient Management,” National Abortion Federation & Planned Parenthood Federation of America “Mifepristone 2000," Pleasant Hill CA, March 2000.

12. “Required Training in Abortion” Training in Abortion: The Next Level, Washington DC, October 2000

13. "Family Planning Fellowships and Planned Parenthood”, PPFA National Medical Committee, Washington DC, December, 2001

14. "Evidence Based Regimen for mifepristone abortions" National Abortion Federation Annual Meeting, San Jose, CA, April 2002

15. “Faculty Models” National Abortion Federation Residency Training Workshop, Phoenix, AZ, December 2002

16. “The Who-What-When-How of Training” National Abortion Federation Residency Training Workshop, Phoenix, AZ, December 2002

17. “Gender Discrimination in Obstetrics and Gynecology: the Impact on recruiting men and retaining women” APGO Faculty Development Seminar, Kapalua, Maui, January 2003

18. “Clinical Issues in First Trimester Abortion”, Medical Students for Choice, Annual Meeting, Seattle, WA, April 2003

19. “Clinical Issues in Second Trimester Abortion”, Medical Students for Choice, Annual Meeting, Seattle, WA, April 2003

20. “Medical Student and Resident Education in Abortion” National Abortion Federation, Annual Meeting, Seattle, WA, April 2003

21. "The Who-What-When-How of Training”, National Abortion Federation Residency Training Workshop,

Chicago, March, 2004

22. "Alternatives to Hysterectomy" Medica Symposia Conference, Maui, Hawaii, December, 2004

23. "Contraceptive Options for Women over 40" Medica Symposia Conference, Maui, Hawaii, December, 2004

24. "Gynecologic Procedures" Medica Symposia Conference, Maui, Hawaii, December, 2004

25. "Workup and Management of Postmenopausal Bleeding" Medica Symposia Conference, Maui, Hawaii, December, 2004

26. "Transcervical Female Sterilization", PPFA Medical Directors Conference, Steamboat Springs, CO, March, 2005

27. "Multi-site Studies", Family Planning Fellowship Directors Meeting, San Francisco, CA, May, 2005

28. "Infections in Medical Abortion" Annual Meeting of the National Abortion Federation, San Francisco, CA April, 2006

29. "Technique of IUD insertion to minimize perforation risk" PPFA teleconference, November 2006

30. "Requiring abortion training in Ob/Gyn residency: Does it effect recruitment?" 34th Annual national meeting of the North American Society for Psychosocial Obstetrics and Gynecology, Portland, OR February 2007

31. "First Trimester Abortion Technique", Medical Students For Choice National Meeting, Tampa, FL, March 2007

32. "Review of Essure Procedures", ASRM, Washington DC, October 2007

33. "Abortion training in Ob/Gyn Residencies" Medical Students for Choice National Meeting, Minneapolis, MN, April 2008

34. "OHSU Feticide Policy" Family Planning Fellowship Annual meeting, New Orleans, LA, May 2008

35. "Balancing Life and Work Panel" ARHP annual meeting, Washington DC, Sept 2008

36. "Update on pain management in surgical abortion". National Abortion Federation annual meeting, Portland, OR, April, 2009.

37. "Management of the non-lethal anomaly". National Abortion Federation annual meeting, Portland, OR, April, 2009.

38. "Pain Management of Gynecologic Procedures" Grand Rounds, Northwestern University, Ob/Gyn department, Chicago, IL May 2009

39. "Essure Review", American Society of Reproductive Medicine annual meeting, Atlanta GA, October 2009

40. "Issues in second trimester abortion", MSFC annual meeting, Salt Lake City, UT, November 2009

41. "Practitioners Perspective Panel", MSFC annual meeting, Salt Lake City, UT, November 2009

42. "Abortion Panel", MEDC meeting, Salt Lake City, UT, March 2010

43. "IUD Review", Grand Rounds, University of Utah Department Ob/Gyn, Salt Lake City, UT, March 2010

44. "Hysteroscopic Sterilization Review" MEDC annual meeting, Las Vegas, NV, March 2011

45. "Patient Safety in Abortion Care", MEDC annual meeting, Las Vegas, NV, March 2011

46. "Pain management in gyn procedures" Grand Rounds, Dept Ob/Gyn, Wayne State University, Detroit MI, March 2011

47. "Values clarification workshop" Residents, Dept Ob/Gyn, Wayne State University, Detroit MI, March 2011

International

1. "Background/Historical Context," "Medications: Mifepristone, Misoprostol and Methotrexate," "Protocol," "Patient Management," National Abortion Federation & Planned Parenthood Federation of America "Mifepristone 2000," Vancouver BC. September 2000

2. "IUD Review", Grand Rounds, Ob/Gyn Department, University of Zambia, Lusaka, Zambia, September 2010

3. "Contraception Review" Hospital Staff Meeting, Gimbie Adventist Hospital, Gimbie Ethiopia, November 2010

4. "Post abortion IUCDs to reduce subsequent pregnancies" International Family Planning Conference, November 2011, Dakar, Senegal

5. "Update on USA contraception research" Shanghai Institute of Planned Parenthood Researach, October 2013

IV. SERVICE

Membership in Professional Societies:

Oregon Medical Association, 1983 - present

American College of Obstetrics and Gynecology, Oregon Section, 1983-present

Multnomah County Medical Society, 1983 - present

Association of Reproductive Health Professionals, 1983 - present

Association of Professors in Gynecology and Obstetrics, 1983 - 1993

American Fertility Society, Elected 1984

National Abortion Federation 1996 - present

National Abortion Rights Action League, 1987 - present

Pacific Northwest Obstetrical and Gynecological Society, 1989 - present

Pacific Coast Obstetrical and Gynecological Society, 1993 – present

Society of Family Planning, 2005 - present

Appointed or Elected Positions in Professional Societies:

American College of Obstetrics and Gynecology, Oregon Section
- Advisory Committee Member, 1984-1987
- Program Coordinator, 1984-1987
- Vice Chair, 1997-2000
- Chair, 2000-2003
- Program Chair, Annual Meeting, April 1998
- Program Chair, Annual Meeting, April 1999
- Program Chair, Annual Meeting, April 2000
- Program Chair, Annual Meeting, April 2001
- Program Chair, Annual Meeting, April 2002
- Program Chair, Annual Meeting, April 2003

American College of Obstetrics and Gynecology, District VIII
- Advisory Council member, 1997-2003
- Junior Fellow Advisor, 2000-2003

Association of Reproductive Health Professionals
- Program Planning Committee, 1998
- Co-Chair, Planning Committee, 2009

National Abortion Federation
- Co-Chair, Risk Management Seminar, 1999
- Co-Chair of Scientific Session at NAF National Meeting
  - Atlanta GA, April 1998
  - Vancouver BC, April 1999
  - Pittsburgh PA, April 2000
  - St. Louis MO, April 2001
  - San Jose, CA, April 2002
  - Seattle, WA, April 2003
  - New Orleans, LA, April 2004
  - Montreal, Canada, April 2005
  - San Francisico, CA, April 2006
  - Boston, MA, April 2007
  - Minneapolis, MN, April 2008
  - Portland, OR, April 2009
  - Philadelphia, PA, April 2010
  - Chicago, IL, April 2011
  - Vancouver BC, April 2012

Pacific Coast Obstetrical and Gynecological Society
- Program Chair, 1998 meeting
- Member program committee, 1997-2003
- Program Chair, 2001 meeting

Society for Family Planning

President Elect, 2007-2009
Chair Scientific Committee, 2007-2009
President, 2009-2011
Immediate Past President, 2011-2013

Editorial and Ad Hoc Review Activities:

Member, Editorial Board

Contraception 2014 - 2018

Journal Reviewer

American Journal of Obstetrics and Gynecology
Obstetrics and Gynecology
Journal of American Women's Association (JAMWA)
British Journal of Obstetrics and Gynecology
New England Journal of Medicine
International Journal of Obstetrics and Gynecology
Contraception

Section Editor

Current Women's Health Reports, General Gynecologic Issues Section, 2001, 2002, and 2003

Committees:
International/National

Norplant Training in the Community, Panel Member, Dallas, Texas, April 1996

Planned Parenthood Federation of America
National Medical Committee, April 1996 - 2002
Primary Care Subcommittee, April 1996 - 2002
Nominating Committee, 1997, 1999
Chair, Nominating Committee, 2001
National Board of Dirctors, 2017-2023

National Abortion Federation
Planning Committee, Risk Management Seminar, Denver CO, September 1999

American College of Obstetrics and Gynecology,
Oregon Section
Advisory Committee Member, 1984-1987

District VIII
Advisory Committee 2000-2003
Junior Fellow Advisor 2000-2003

Association of Reproductive Health Professionals
Program Planning Committee, 1998, 2008

Regional

Pacific Coast Obstetrical and Gynecological Society, 1993 - present
Member program committee, 1997-2003

Institutional

OHSU School of Medicine
Grievance Committee, September 1985 - June 1989
Joint Conference Committee on Graduate Medical Education, January 1987 - 1994
Student Health Advisory Committee, January 1988 - June 1994
Curriculum Review Task Force, Transition to Residency Course, February 1991 - 1993
Faculty Council, August 1991 - June 1997
Faculty Senate, June 1994- June 1996
Search Committee for Director for Maternal Fetal Medicine Division, 1998
Promotion and Tenure, October 1996 - 2002
Women's Health Student Interest Group, Faculty Advisor, 1998 - present
Medical Students for Choice, OHSU Chapter, Faculty Advisor, 1998 - present
School of Medicine Awards Committee, 2002-2007
Faculty Practice Plan Board of Directors, elected member, 2009-2012

Departmental

Executive Committee 1988-present
Promotion and Tenure Committee 1995-present
Clinical Care Committee 1999-present
Education Committee 1999-present
Combined Education Committee 1983-1995

Hospital

Medical Records Committee, September 1983 - 1987
Ambulatory Care Committee, July 1987 - July 1990
Operating Room Committee, 1988 - 1992
University Medical Group
Finance Committee, April 1993 - April 1997
Clinical Practice Committee, May 1994 - April 1997
Board of Directors, Specialty Care Representative, March 1998 - 2001
Compensation Committee, 1998
Board of Directors, 1998 - 2001
IPCO Advisory Board, 1995 - 1998
University Hospital North, Ambulatory Surgery Move Task Force, March 1997 - June 1998
Surgical Services Committee, 1998 - present
Ambulatory Surgery Management Group, 2000 - 2003.

Local, State, National Recognition for Clinical Excellence:

Selected as one of the "Top-Rated Physicians in America", in Guide to Top Doctors, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012
Named as one of the "Best Doctors for Women-coast to coast", *Ladies Home Journal*, April, 2002
Selected as one of "Our Best Doctors" by Portland physicians, *Portland Monthly*: 2004, 2005, 2006, 2007, 2008,

2009, 2010, 2011, 2013
"Pioneer and Leader Award", for introduction of Essure in PPFA, September 2004

Clinical Care Awards:

Rose Awards: numerous

Community Service:

Birth Home, Board of Directors, Portland OR, 1982 - 1987
Planned Parenthood Columbia Willamette
Medical Committee, April 1984 - present
Chairman Medical Committee, June 1991 - 1994
Board of Directors, July 1991 – 1994 and June 2016 to present
Portland Feminist Women's Health Center, Medical Advisor, 1983 - 1987
Oregon State Health Division
Out of Hospital Birth Task Force, September 1985 - November 1987
Direct Entry Midwifery, Board of Directors, 1993 - 1999
Family Planning Consultant, April 1997 - present
Teen Pregnancy Prevention Task Group Member, December 1996 - present
Region X Chlamydia Project Member, February 1997 - present
Population Services International
Advisory Committee on Emergency Contraception Promotion Project 2000-2001

V. TEACHING (OHSU Educator's Portfolio):

Overview of your Role as an Educator:

Almost all of my clinical activities occur with a learner present. I see patients at the Center for Women's Health with third year medical students, provide care at Planned Parenthood with Ob/Gyn residents and Family Planning fellows, perform surgery and deliver babies with medical students and residents. My philosophy of teaching is to allow learners to perform to their abilities and to encourage assumption of increasing responsibility as skills and knowledge grow. I believe that learning occurs best when individuals are given autonomy (commensurate with their training) to provide medical care. I attempt to foster this type of learning by providing feedback during and after the learners care for patients. In surgery, that occurs while directing every action of the learners. In the clinic setting, the learners have more independence to develop their skills without step by step direction.

Scholarship of Teaching:

Curriculum Development

I developed the program objectives for the Family Planning Fellowship. This document was submitted to the Buffett Foundation, and we received approval as a training site.

Educational Conference Presentations

See "Invited Lectures, Conference Presentations or Professorships:" (above)

Classroom Teaching (Since 1995, and not cited in Local Presentations above)

Principles of Clinical Medicine,

"Obstetric Physical Examination", 1995, 1996, 1997, 1998, 2000, 2001, 2002, 2003, 2004, 2005
Pelvic/GU Examination Instructor, 1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010

Gross Anatomy Class – MS I Course:
Instructor 2001, 2003, 2004

Physician Assistant Curriculum
"Breast Disease" 1999, 2001
"Contraception" 1999, 2001
"Ectopic Pregnancy" 2003, 2004, 2005, 2006, 2007

Human Growth and Development - MS II Course
"Contraception, Abortion, and Sterilization" 1995-2012
"Female Infertility" 1995-2001
"Abnormal Menstrual Cycles" 1995-2004
"Panel: Population Growth", 1995-1998

Pediatric Resident Noon Conference Series
"Contraception for Adolescents," 1996, 1998, 2000, 2003
"Evaluation and Management of Abnormal Bleeding in Adolescents," 2000, 2002

Internal Medicine Resident Noon Conference Series
"Contraception Review", 2004

Students for Reproductive Choice Elective
"Surgical Abortion Technique" 1997-2007

Women's Health Care Nurse Practitioner Curriculum
"Abortion Review" 1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002, 2003
"Benign Breast Disease" 1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002, 2003
"Oral Contraceptives and Emergency Contraception" 2002, 2003

Nurse-Midwifery Curriculum
"Shoulder Dystocia" 1995-2016
"Breech Presentation" 2006, 2008, 2010, 2012, 2014, 2016

Family Practice Resident Noon conference
"Contraception Update" 2003
"Medical Abortion" 2003

Endocrinology Fellows Noon Conference
"Contraceptive Review" 2005

Women's Health Interest Group
"Management of Breech Presentation" 2010

Education Grants and Contracts:

Fellowship in Family Planning, funded by the Buffett Foundation. This pays for the salary of two fellows (R5 & R6) and 10% of the faculty of the fellowship director, (split evenly with the assistant fellowship director)

Effectiveness of Educational Activity:

Evaluations from teaching activities are available.

Mentorship:

Served on the MPH thesis committee for Kim Goldsmith, 2003-2004.
Served as mentor of numerous residents for their research projects including Lisa Thomas, Alison Edelman, Neva Phair, Carla Picardo, Marni Kwiecen, Liz Morgan, Gary Burgoine, Stephanie Koontz, Gina Allison, Emily Drath

Service and Membership of Educational Committees:

Steering Committee for the Human Growth and Development Course, SOM, OHSU, 1995-2002
Course Development Committee, Transition to Internship, SOM, OHSU, 1998
Member, Thesis Advisor for Kim Goldsmith, candidate for MPH, 2003

Honors and Awards for Education:

Outstanding Teaching Award, presented by graduating chief residents, OB/GYN Department at OHSU, June 1992.

APGO/CREOG National Faculty Award, presented for excellence in teaching to one faculty member in the Ob/Gyn Dept. at OHSU each year, June 1993.

Excellence in Basic Sciences Teaching MSII Curriculum, OHSU, School of Medicine, 1994-1995.

Teaching Excellence Award, OHSU, School of Medicine, 1999-2000

J. David Bristow Award, OHSU, School of Medicine, Senior Class recognition to "one faculty member who exemplifies the ideals of the true physician as he/she conducts clinical practice with patients and colleagues", June 2001.

APGO/CREOG National Faculty Award, presented for excellence in teaching to one faculty member each year, June 2001

Planned Parenthood Federation of America, Affiliate Excellence Award given to one affiliate in the country for outstanding clinical teaching and research, 2003

Chosen as Faculty Marshal, OHSU School of Medicine Commencement Ceremony, June, 2004

Teaching Excellence Award, OHSU, School of Medicine, 2003-2004

Medical Students for Choice Faculty Mentor Award, presented at MSFC National meeting, Philadelphia, March, 2005

J. David Bristow Award, OHSU, School of Medicine, Senior Class recognition to "one faculty member who exemplifies the ideals of the true physician as he/she conducts clinical practice with patients and colleagues", June 2007.

The Leonard Tow Humanism in Medicine Award, June 2007

Chosen as Faculty Marshal, OHSU School of Medicine Commencement Ceremony, June, 2008

Outstanding Teacher Award, presented by graduating chief residents, OB/GYN Department at OHSU, June 2009.

Medical Students for Choice Faculty Mentor Award, presented at MSFC National meeting, Salt Lake City, UT, October 2009.

Robert Hatcher Family Planning Mentor Award, Society of Family Planning, 2015

Medico-Legal activities:

Testimony and depositions:

Date	Lawyer	Name	Location
8/7/07	John Hart	Warling v Newhall	Oregon
9/25/07	Larry Brisbee	Fino-Morales v Providence	Oregon
11/30/07	Kelly Giampa	Brown v Newhall	Oregon
1/10/08	Kim Hoyt	Jones v Peterson	Oregon
2/26/08	John Hart	Kluschkowski v Peacehealth	Oregon
11/3/08	Michael Ramsden	Dusbabek v Ambrose	Idaho
May 2009	John Hart	Wharton v Grant	Oregon
8/25/11	Ed Lemons	Hayes v Price	Nevada
11/6/11	TroyBundy	Nguyen v Draper	Oregon
11/20/14	Larry Brisbee	Bergstrom v Carbonell	Oregon
	Sherry Browning	Bergstrom v Carbonell	Oregon
2/6/20	Chip Horner	Ziadi-Hadar v A Gentle Beginnings	Oregon

Other Legal Activities

Date	Lawyer	Name	Activity	Location
10/6/16	Laura Einstein	State of Idaho v Planned Parenthood	Deposition	Boise, Idaho
3/24/17	Alexa Kolbi-Molinas	ACLU v Commonwealth of Kentucky	Testimony	Lexington, Kentucky
11/8/17	Janet Crepps	Center for Reproductive Rights vs Texas	Testimony	Austin, Texas
4/5/19	Chip Horner	Maria Espuro vs Bayer	Deposition	Portland, OR
2/1/19, 5/20/19, 5/31/19	Jenny Ma	Falls Church Medical Center vs Norman Oliver	Deposition and testimony	Portland, OR Richmond, VA

Exhibit 1-2

IN THE DISTRICT COURT OF OKLAHOMA COUNTY
STATE OF OKLAHOMA

(1) SOUTH WIND WOMEN'S CENTER LLC, D/B/A TRUST WOMEN OKLAHOMA CITY, on behalf of itself, its clinicians and staff, and its patients; and (2) COLLEEN MCNICHOLAS, D.O., on behalf of herself and her patients; and (3) BRIDGET VAN TREESE, M.S.N., APRN-CNP., on behalf of herself and her patients, Plaintiffs, v. (1) MIKE HUNTER, in his official capacity as Attorney General of Oklahoma; and (2) DAVID PRATER, in his official capacity as Oklahoma County District Attorney; and (3) LYLE KELSEY, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision; and (4) G. ROBINSON STRATTON, III, in his official capacity as Executive Director of the Oklahoma State Board of Osteopathic Examiners; and (5) KIM GLAZIER, in her official capacity as the Executive Director of the Oklahoma Board of Nursing; and (6) GARY COX, in his official capacity as Oklahoma Commissioner of Health, Defendants.	)	Case No. CV-2019-2506 Hon. Judge N. Mai

DECLARATION OF DANIEL A. GROSSMAN, M.D. IN SUPPORT OF PLAINTIFFS' REPLY MOTION FOR A TEMPORARY INJUNCTION

DANIEL A. GROSSMAN, M.D., declares and states as follows:

1. I submit this declaration in support of Plaintiffs' Reply in Support of their Motion for a Temporary Injunction, which seeks to enjoin enforcement of 63 O.S. § 1-729.1 (the "Physician In-Person Law") and 63 O.S. § 1-731(A) (the "Physician-Only Law") (together, the "Challenged Laws"). More specifically, this declaration responds to the opinions offered by Dr. Donna Harrison in support of Defendants' opposition to the Plaintiffs' motion.

2. The opinions in this declaration are based on my education, clinical training, experience as a practicing physician over the past twenty-six years, my medical research, regular review of other medical research in my field, and attendance at professional conferences. My background is more extensively set forth in an affidavit I submitted in support of Plaintiffs' Motion for a Temporary Injunction.[1] The facts in this declaration, unless otherwise stated, are based on my personal knowledge.

Medication Abortion is Safe

3. As I discussed in my previous affidavit, under any measure of safety, medication abortion is a safe medical treatment and a safe method of abortion.[2] Numerous major, peer-reviewed studies—including several relied on by the U.S. Food and Drug Administration ("FDA") in approving an updated label for Mifeprex in 2016[3]—demonstrate the safe and effective use of mifepristone for medication abortion up to ten weeks (70 days) of gestation. As discussed in further detail below, Dr. Harrison's opinions about the safety of medication abortion are not supported by the medical literature.

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[1] *See* Grossman Aff. ¶¶ 1-4.
[2] *See* Grossman Aff. ¶ 19.
[3] U.S. Food & Drug Administration (FDA), *Mifeprex Label 2016*, 7 (2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf [hereinafter "Mifeprex Label"].

4. Dr. Harrison's declaration selectively quotes data from the FDA's Mifepristone Adverse Events Summary ("Summary"), and, moreover, it fails to provide any context for the data.[4] The Summary reports adverse events over a period of 18 years, during which time approximately 3.7 million women have received medication abortion using mifepristone for medical termination of pregnancy. Therefore, the hospitalization rate is 0.028% (1,042/3,700,000), the blood transfusion rate is 0.016% (599/3,700,000), and the infection rate is 0.011% (412/3,700,000).[5] These numbers are consistent with those reported in peer-reviewed studies.[6] However, Dr. Harrison omits this information from her declaration, even though it is included in the FDA's Summary.

5. Moreover, Dr. Harrison's declaration focuses on the 24 deaths linked to medication abortion reported in the Summary, but omits that 11 of those 24 deaths do not appear related to medication abortion.[7] Six of the deaths were related to drug use, overdose, or intoxication, two were homicides, one was a suspected homicide, one was due to suicide, and one resulted from emphysema.[8] In addition, seven deaths were due to *C. sordellii* (Clostridium) infections,[9] but there is no causal link between medication abortion and Clostridium infection.[10] Indeed, the FDA label for Mifeprex states: "No causal relationship between the use of MIFEPREX and misoprostol and

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[4] *See* Harrison Decl. ¶ 12.
[5] U.S. Food & Drug Administration (FDA), RCM # 2007-525, Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/13/2018, at 1-2, https://www.fda.gov/media/112118/download [hereinafter "FDA Post-Marketing"].
[6] *See, e.g.*, Kelly Cleland et al., *Significant Adverse Events and Outcomes After Medical Abortion*, 121 OBSTET. & GYNECOL. 166, 169 (2013); Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 OBSTET. & GYNECOL. 175, 175 (2015).
[7] FDA Post-Marketing at 1.
[8] *Id.*
[9] *Id.*
[10] American College of Obstetricians and Gynecologists, Practice Bulletin No. 143: Medical Management of First-Trimester Abortion, 8 (Mar. 2014, reaffirmed 2016) [hereinafter "AGOC Bulletin"].

[fatal infections and bleeding] has been established."[11] Further, the FDA clinical review team confirmed that "[s]ince 2009, there have been no *C. sordellii* deaths associated with medical abortion in the U.S."[12] That there are only 13 deaths cited in the Summary that are possibly related to the abortion, out of 3.7 million patients, illustrates the extremely low mortality rate resulting from medication abortions.

6. Consistent with these low rates of adverse events, a recent large-scale study that reviewed the outcomes of 233,805 medication abortions performed in the United States found that only 0.16% of patients experienced a significant adverse event (defined as hospital admission, blood transfusion, emergency department treatment, intravenous antibiotics administration, infection requiring treatment with intravenous antibiotics or admission to the hospital, or death).[13] My 2017 study of over 19,000 medication abortions in Iowa found that only 0.26% of patients experienced a clinically significant adverse event.[14] Another study that I co-authored in 2015 examined complications from approximately 55,000 abortions among California Medicaid patients and found a major complication rate of 0.31% for medication abortion patients.[15]

7. Dr. Harrison also incorrectly interprets information from the FDA Mifeprex label.[16] The label clearly states that ***serious adverse reactions***—which include transfusion, infections, and hemorrhage—occur in less than 0.5% of women.[17] However, Dr. Harrison groups the "***adverse***

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[11] Mifeprex Label at 2.
[12] U.S. Food & Drug Admin., Ctr. for Drug Evaluation and Research, No. 020687Orig1s020, Med. Rev., 83 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf [hereinafter "FDA Med. Rev."].
[13] Cleland et al., *supra* note 6, at 168-69.
[14] Daniel Grossman & Kate Grindlay, *Safety of Medical Abortion Provided Through Telemedicine Compared With In Person*, 130(4) OBSTET. & GYNECOL. 778, 781 (Oct. 2017).
[15] Upadhyay et al., *supra* note 6, at 181.
[16] *See* Harrison Decl. ¶¶ 10-11.
[17] Mifeprex Label at 7-8.

reactions" together with "***serious adverse reactions***" to incorrectly suggest that 85% of patients report "***serious adverse reactions***."[18] The most common "adverse reactions," occurring in more than 15% of patients, are "nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness."[19] The label later describes these same reactions as "side effects."[20] While these side effects may be uncomfortable, they do not suggest that mifepristone is dangerous or unsafe. Women who have decided to have a medication abortion are advised of these side effects and are instructed on how to address them.[21] They are given instructions on when to seek medical care, as with any prescription medication, and they are provided the contact information for their providers as an additional precaution.[22]

8. Dr. Harrison also mischaracterizes and omits key information when she excerpts information from the "black box warning" of the Mifeprex label.[23] Dr. Harrison quotes the label as stating: "Warning: Serious and Sometime Fatal Infections or Bleeding."[24] However, she does not fully quote the label, which goes on to read: "Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following MIFEPREX use. No causal relationship between the use of MIFEPREX and misoprostol and these events has been established."[25] Omission of this key information gives the false impression that infections are more common and dangerous than they actually are, and it

[18] *See* Harrison Decl. ¶ 10 ("'About 85% of patients report at least one adverse reaction . . . .' These reactions include, but are not limited to, vomiting, headache, uterine hemorrhage, viral infections, and pelvic inflammatory disease.").
[19] Mifeprex Label at 7.
[20] *Id.* at 19.
[21] *Id.* at 18 (listing these as possible symptoms after taking Mifeprex in the "Medication Guide," which is handed to patients).
[22] *Id.* at 16.
[23] *See* Harrison Decl. ¶ 11.
[24] *Id.*
[25] Mifeprex Label at 2.

falsely insinuates that they are caused by Mifeprex—in direct contradiction to the language on the label.

9. Dr. Harrison also notes that Mifeprex has a Risk Evaluation and Mitigation Strategy ("REMS"),[26] but the presence of a REMS does not contradict or undermine the well-established safety record of medication abortion. As outlined in my 2017 article, REMS "are intended for drugs that are known or suspected to cause serious adverse effects that cannot be mitigated simply by the label instructions," but "the Mifeprex elements do not meet these specifications. Mifepristone is not inherently toxic or harmful to the woman using it."[27] Notably, other countries such as Australia and Canada have not imposed safety regulations analogous to the REMS, and have not encountered substantial safety concerns when administering mifepristone.[28] The two serious risks described on the Mifeprex label are also not unique to the drug. They occur after many other common obstetrical and gynecological procedures that are not subject to the same regulations as medication abortion.[29] The "rationale for singling out Mifeprex as needing such measures to ensure safety is lacking, and the Mifeprex elements can hardly be justified as 'commensurate' with the risks"—as the safety information included on the FDA-approved Mifeprex label itself makes clear.[30]

Medication Abortion is as Safe as Surgical Abortion

10. Dr. Harrison incorrectly asserts that medication abortions are more dangerous than surgical abortions.[31] Medication abortions have an extremely low complication rate relative to

[26] Harrison Decl. ¶ 11.
[27] Mifeprex REMS Study Group, *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 376(8) NEW ENGL. J. MED. 790, 790-793 (2017).
[28] *Id.* at 792.
[29] *Id.*
[30] *Id.*
[31] *See* Harrison Decl. ¶¶ 15-18.

other medical procedures, including surgical abortion. While it is true that the "failure rate" for medication abortion, *i.e.*, the proportion of women who require a vacuum aspiration to complete the abortion, is higher than the proportion of women who undergo a surgical abortion and require a repeat procedure, this does not make medication more risky. In fact, it is a known feature of the method that is clearly explained to patients during the counseling process.

11. Further, as is the case in all other medical contexts, it should be up to the patient, in consultation with her medical provider, to weigh the risks and benefits of medication versus surgical abortion. As I discussed in my previous affidavit, medication abortion has certain notable advantages over surgical abortion (*e.g.*, it affords greater flexibility with respect to timing, avoids the use of anesthesia or sedation, and is less invasive and more private), and it is medically preferable for those with certain medical or anatomical conditions.[32] Moreover, the relative risk of surgical abortion is not at all relevant to the question of whether medication abortion may be safely practiced via telemedicine or by advanced practice registered nurses ("APRNs").

Medication Abortion via Telemedicine is Safe

12. As discussed at length in my prior affidavit, medication abortion can be safely provided via telemedicine.[33] Contrary to Defendants' arguments, Plaintiffs' data about the safety of medication abortion when administered by telemedicine is not based solely on data from the Planned Parenthood clinics in Iowa. The most recent telemedicine-specific study relies on data from multiple states, including Alaska, Idaho, Nevada, and Washington.[34]

[32] *See* Grossman Aff. ¶¶ 21-23.
[33] *Id.* at ¶¶ 25-31.
[34] *Id.* at ¶ 29 (citing Julia E. Kohn & Jennifer Snow, *Medication Abortion Provided Through Telemedicine in Four U.S. States*, 134 OBSTET. & GYNECOL. 343 (2019)).

13. Further, I disagree with Dr. Harrison's opinions about telemedicine. First, I do not believe that providing care via telemedicine "trivializes" the seriousness of that care.[35] Telemedicine is widespread around the country, and has not "trivialized" the care provided through this means. In fact, a recent systematic review found that telemedicine is used for a variety of services related to women's health.[36]

14. Secondly, I disagree with Dr. Harrison's opinion that telemedicine precludes a thorough evaluation before medication abortion.[37] An ultrasound, which I understand is part of the Trust Women protocol for medication abortion via telemedicine, permits detection of an intra-uterine pregnancy and excludes an ectopic pregnancy to the same degree as when a patient is evaluated in person. The presence of an intra-uterine device ("IUD") is generally excluded by patient history and may also be confirmed by ultrasound. Neither the ACOG Practice Bulletin nor the FDA labeling for Mifeprex requires a physical exam to provide medication abortion.[38]

15. Finally, I disagree with Dr. Harrison's concerns about complications following a medication abortion via telemedicine.[39] I understand that Trust Women, like many clinics, provides its patients with information about a follow-up appointment, a phone number for after-hours concerns, and information on potential side-effects of the procedure. Patients receive the care they need for medication abortion—whether provided via telemedicine or during an office visit. In our cohort study in Iowa, we found that patients receiving medication abortion by telemedicine were just as likely to return to the clinic for follow-up as were patients who had a

[35] Harrison Decl. ¶ 29.
[36] Nathaniel DeNicola et al., *Telehealth Interventions to Improve Obstetric and Gynecologic Health Outcomes: A Systematic Review*. 135(2) OBSTET & GYNECOL 371 (2020).
[37] Harrison Decl. ¶¶ 30-38.
[38] *See* Mifeprex Label; ACOG Bulletin.
[39] Harrison Decl. ¶¶ 39-43.

medication abortion with an in-person visit.[40] In addition, our study of almost 20,000 patients undergoing medication abortion in Iowa used safety outcome information that all physicians are required to report to the drug's manufacturer and the FDA. Therefore, we would have captured adverse events that were detected at clinical sites other than the abortion clinic,[41] whether the treatment was provided in person or via telemedicine.[42]

APRNs Can Safely Provide Medication Abortion

16. Defendants assert that "safety and other reasons" justify preventing APRNs from performing medication abortions, without explanation or evidentiary support.[43] In fact, Defendants' position is contrary to well-accepted research and the positions of leading medical authorities. ACOG states that medication abortion "can be provided safely and effectively by nonphysician clinicians."[44] The FDA explicitly allows for non-physicians to provide medication abortions.[45] Moreover, several studies have confirmed that non-physicians can safely provide abortions.[46]

Dr. Harrison Misrepresents the Medical Literature on the Safety of Medication Abortion

17. Dr. Harrison misconstrues data from the FDA and major peer-reviewed studies, and instead relies upon outdated and unreliable studies to support her opinions. Dr. Harrison asserts that the FDA fails to adequately monitor complications.[47] She relies on a study she co-authored

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[40] Daniel Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*, 118 OBSTET. & GYNECOL. 296, 302 (2011).
[41] Grossman & Grindlay, *supra* note 14, at 779.
[42] *Id*.
[43] Opp. Br. at 14.
[44] ACOG Bulletin at 11.
[45] FDA Med. Rev. at 7; Mifeprex Label (uses term "healthcare provider" rather than "physician" throughout).
[46] *See, e.g.*, Helena Kopp Kallner, et al., *The Efficacy, Safety and Acceptability of Medical Termination of Pregnancy Provided by Standard Care by Doctors or by Nurse-Midwives: A Randomized Controlled Equivalence Trial*, 122(4) Brit. J. OBSTET. & GYNECOL. 510, 515 (2014).
[47] Harrison Decl. ¶ 13.

that reviewed FDA Adverse Event Reports from 2000 through 2004.[48] These data are from the first four years Mifeprex was used for medication abortion in the United States and are over fifteen years old. Her study implies that the adverse event rate is underreported, but that assertion is speculative. Dr. Harrison fails to acknowledge the subsequent robust review of adverse events based not only on FDA reports, but also U.S. clinical studies published in peer-reviewed journals. Neither her article nor her declaration support the conclusion that complications are unknown or widely underreported.

18. The FDA carefully monitors reports of complications, and the agency's data are as complete for mifepristone as they are for any other FDA-approved drug. Nearly two decades of post-market experience and clinical studies have confirmed that medication abortion is safe and effective.[49]

19. Specifically, the FDA's recent review of 15 years of post-market experience and updated clinical studies highlights the overall safety and efficacy of medication abortion.[50] The FDA's efficacy review in connection with proposed changes to the Mifeprex label evaluated the quality of the studies that supported the current label, including whether the literature was an adequate primary information source to support the FDA's conclusion that the current medication abortion protocol is safe. Moreover, the FDA's medical review provides detailed information regarding the medical literature reviewed by the FDA and its reasons for approving the label

[48] Margaret M. Gary & Donna J. Harrison, *Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient*, 40 ANNALS PHARMACOTHERAPY 1, 1 (2006).
[49] *See* Regina Kulier et al., *Medical Methods for First Trimester Abortion (Review)*, COCHRANE DATABASE OF SYSTEMATIC REVS., Issue 11 (Nov. 2011).
[50] *See* FDA Med. Rev. at 47-76; *see also* U.S. Food & Drug Admin., Ctr. for Drug Evaluation and Research, No. 020687Orig1s020, Summary Rev., 10-12 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020SumR.pdf [hereinafter "FDA Summary Rev."].

update. The 14 major studies and literature reviews relied upon by the FDA in approving the updated label are listed at Table 1 of the FDA's Medical Review.[51] The FDA's clinical review team identified key serious adverse events—including hospitalization, serious infection, bleeding requiring transfusion, and ectopic pregnancy—discussed in the medical literature.[52] The FDA team noted that, in U.S., hospitalization rates associated with medication abortion ranged from 0.04% to 0.6% (in a population of over 14,000 women); serious infection occurred in 0% to 0.2% of cases (in a population of over 12,000 women); and rates of transfusion were 0.03% to 0.5% (in a population of over 17,000 women).[53] These rates of adverse events are well within the range of an acceptable level of risk for a medical treatment.[54] The FDA noted that the regimen "has been studied extensively in the literature using U.S. and global sites"[55] and concluded that major adverse events were "exceedingly rare."[56]

20. Dr. Harrison is also wrong in her analysis of the 2015 Upadhyay study, which analyzed complication rates resulting from abortions in more than 50,000 California Medicaid patients.[57] The study, which I co-authored, reviewed billing codes to evaluate the type of medical care patients received following an abortion, both at the location where they received the abortion and at other locations, including the emergency department. Because the study's methodology captured all care women received post-abortion, it is one of the most thorough and reliable studies on abortion complications. Dr. Harrison criticizes this study by suggesting that its definition of

[51] *See* FDA Med. Rev. at 18, Table 1; *see also* FDA Med. Rev. at 91-98, App. 9.5, for the full list of references reviewed by the FDA.
[52] FDA Summary Rev. at 10.
[53] *Id.* at 10-11.
[54] FDA Med. Rev. at 47.
[55] FDA Summary Rev. at 11.
[56] FDA Med. Rev. at 47.
[57] *See* Harrison Decl. ¶ 27; Upadhyay et al., *supra* note 6.

"major" complications is unduly narrow.[58] This is not true; the study defines "major" complication broadly to include "serious unexpected adverse events requiring hospital admission, surgery, or blood transfusion."[59] This definition is similar, if not more inclusive, than the FDA's definition of a "serious adverse event."[60]

21. Dr. Harrison suggests that "emergency room visits" should also be included in the safety assessment.[61] In our study of more than 19,000 medication abortions in Iowa, we did document the frequency of emergency department visits where treatment was given, and these visits were very rare.[62] Among 8,765 medication abortions provided by telemedicine, there were 13 cases of emergency department visits where treatment was given (0.15%).[63] Among 10,405 medication abortions provided with an in-person visit, there were 22 cases of emergency department visits where treatment was given (0.21%).[64] The prevalence of these visits was very low in both groups and did not differ to a statistically significant extent between telemedicine and in-person provision.

22. In her declaration, Dr. Harrison expresses concern that hemorrhage without transfusion is not considered a major complication. She notes that she has reviewed FDA adverse event reports where patients lost "nearly half of their blood—without [receiving] a transfusion."[65] Given that the average person has a blood volume of approximately five liters, this would mean losing approximately 2500 cc of blood. It is unfortunate that Dr. Harrison did not provide more

[58] *See* Harrison Decl. ¶ 27.
[59] Upadhyay et al., *supra* note 6, at 176.
[60] *See* Mifeprex Label at 7-8 (defining "serious adverse event" as including transfusion, infections, and hemorrhage).
[61] *See* Harrison Decl. ¶ 27.
[62] Grossman & Grindlay, *supra* note 14.
[63] *Id.* at 781.
[64] *Id.*
[65] Harrison Decl. ¶ 27.

information about these cases, since it would be very unusual to have such a massive hemorrhage and not require a transfusion. The problem is that hemorrhage does not have a standard definition and may be interpreted to mean any degree of bleeding. Given that bleeding is an expected symptom of medication abortion, unquantified hemorrhage is not necessarily a sign of an adverse event—and certainly not a major one.

23. The study found that only 3.1 out of 1,000 patients (0.31%) in this study experienced a major complication (hospital admissions, surgery, or blood transfusion) following a medication abortion.[66] By contrast, nearly 3% (i.e., ten times higher than for medication abortions) of all women who give birth vaginally have a prolonged hospital admission or early re-admission to the hospital. For cesarean delivery (a major operation that more than 30% of American women who give birth will undergo), the figure is three times higher.[67]

24. Dr. Harrison also ignores that the study included an analysis of all "complications"—not just those defined as "major"—and employed an extremely broad definition. The study "defined a complication as any postabortion adverse event that received an abortion-related diagnosis or treatment at any source of care, including EDs [emergency departments] and the original abortion facility within 6 weeks of an abortion procedure."[68] Even following that broad definition of "complication," the study reported only a 5.2% rate of

[66] Upadhyay et al., *supra* note 6, at 175.
[67] Patricia R. Hebert et al., *Serious Maternal Morbidity After Childbirth: Prolonged Hospital Stays and Readmissions*, 94 OBSTET. & GYNECOL. 942, 944 (1999); Brady E. Hamilton et al., *Births: Preliminary Data for 2011*, 61 NAT'L VITAL STAT. REP. 1, 2 (Oct. 3, 2012), https://www.cdc.gov/nchs/data/nvsr/nvsr61/nvsr61_05.pdf.
[68] Upadhyay et al., *supra* note 6, at 179.

complications for medication abortions.[69] The study also posits multiple reasons why it may have *over-reported* complications.[70]

25. The studies Dr. Harrison relies on to assert that "[medication abortion] complications are common" are inferior to the studies relied upon by the FDA and by Plaintiffs.[71] Both the Mulligan study[72] and the Niinimaki study[73] have serious methodological limitations. The Mulligan study has a small sample size[74] and does not control for the route of misoprostol administration or timing of misoprostol administration.[75] The Niinimaki study does not differentiate between different medication abortion protocols.[76] The Niinimaki study also does not define how hemorrhage was quantified.[77] And in any event, the Mulligan study concludes that "the rate of any adverse outcome following early abortion is low" and that "little can be made of the likelihood of the most serious adverse outcomes of early abortion except to note that they are rare."[78] The Niinimaki study finds that there is a "low level of serious complications"[79] and medical and surgical abortion are "generally safe."[80]

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[69] *Id.* at 181.
[70] *See id.* at 182.
[71] Harrison Decl. ¶¶ 24-27.
[72] Ea Mulligan & Haley Messenger, *Mifepristone in South Australia: The First 1343 Tablets*, 40(5) AUSTRALIAN FAMILY PHYSICIAN 342 (2011).
[73] Maarit Niinimaki et al., *Immediate Complications After Medical Compared with Surgical Termination of Pregnancy*, 114(4) OBSTET. & GYNECOL. 795 (2009).
[74] Mulligan & Messenger, *supra* note 72, at 343 (947 medication abortion in the sample compared to 233,805 medication abortions in the sample in Cleland et al., *supra* note 6, and 11,319 medication abortion in the sample in Upadhyay et al., *supra* note 6).
[75] *Id.*
[76] Niinimaki et al., *supra* note 73, at 796.
[77] *Id.* at 799-800.
[78] Mulligan & Messenger, *supra* note 72, at 343-44.
[79] Niinimaki et al., *supra* note 73, at 803.
[80] *Id.* at 798.

26. Dr. Harrison cites to an "abortion reversal" study as part of her claim that there is a high risk of hemorrhage following medication abortions.[81] This study was designed to test a claim that medication abortions are "reversable" and was conducted by having the patient take only mifepristone, but not misoprostol, the second drug in the medication abortion regimen.[82] The higher rate of hemorrhage confirmed the importance of the two-drug regimen for medication abortion. As a result, the "reversal" study says nothing about the safety of the current protocol for medication abortion, which requires the administration of both drugs. This protocol is extremely safe, as demonstrated by the fact that serious adverse reactions, including hemorrhage, occur in less than 0.5% of women who undergo the treatment.[83]

Conclusion

27. The Challenged Laws present arbitrary, burdensome, and unreasonable restrictions on the provision of medication abortion that serve no legitimate medical purpose in light of the safety of that treatment.

28. Dr. Harrison misrepresents existing studies and relies on outdated or debunked information to suggest that medication abortion is dangerous, when—in fact—the data, research, and credible peer-reviewed studies show it is extremely safe.

29. It is my opinion that Oklahoma's prohibition on the delivery of medication abortion via telemedicine and by APRNs burdens women's access to medication abortion for no medically justifiable reason.

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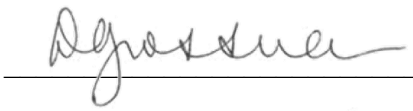
[81] *See* Harrison Decl. ¶ 20.
[82] *See* Mitchell D. Creinin et al., *Mifepristone Antagonization with Progesterone to Prevent Medical Abortion*, 135(1) OBSTET. & GYNECOL. 158 (2020).
[83] Mifeprex Label at 7-8.

I declare under penalty of perjury that the foregoing is true and correct.

Dated this 30th day of January, 2020.



Daniel A. Grossman, M.D.

Exhibit 1-3

No. 20-50264

In the United States Court of Appeals *for the* Fifth Circuit

In re: GREGG ABBOTT, in his official capacity as Governor of Texas; KEN PAXTON, in his official capacity as Attorney General of Texas; PHIL WILSON, in his official capacity as Acting Executive Commissioner of the Texas Health and Human Services Commission; STEPHEN BRINT CARLTON, in his official capacity as Executive Director of the Texas Medical Board; KATHERINE A. THOMAS, in her official capacity as the Executive Director of the Texas Board of Nursing, *Petitioners*.

On Petition for Writ of Mandamus to the
United States District Court for the Western District of Texas
Case No. 1:20-CV-323, Hon. Lee Yeakel

BRIEF OF AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN MEDICAL ASSOCIATION, AND OTHER NATIONWIDE ORGANIZATIONS OF MEDICAL PROFESSIONALS AS *AMICI CURIAE* IN OPPOSITION TO THE PETITION FOR A WRIT OF MANDAMUS

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SUPPLEMENTAL STATEMENT OF INTERESTED PERSONS

No. 20-50264, *In re Gregg Abbott et al.*

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Fifth Circuit Rule 28.2.1, in addition to those disclosed in the parties' statements of interested persons, have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

Amici Curiae	**Counsel**
1. States of Alabama, Arkansas, Idaho, Indiana, Kentucky, Louisiana, Mississippi, Missouri, Nebraska, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, Utah, and West Virginia	1. Louisiana Department of Justice (Elizabeth Murrill; J. Scott St. John) 2. Lill Firm, P.C. (David S. Lill)
1. American Center for Law & Justice	1. American Center for Law & Justice (Edward Lawrence White)
1. American College of Obstetricians and Gynecologists 2. American Medical Association 3. American Academy of Family Physicians 4. American Academy of Nursing	1. Mayer Brown (Nicole A. Saharsky; Kathleen S. Messinger) 2. American College of Obstetricians and Gynecologists (Skye L. Perryman)

5. American Academy of Pediatrics 6. AAGL 7. American College of Nurse-Midwives 8. The American College of Osteopathic Obstetricians and Gynecologists 9. American College of Physicians 10. American Osteopathic Association 11. American Psychiatric Association 12. American Society for Reproductive Medicine 13. American Urogynecologic Society 14. North American Society for Pediatric and Adolescent Gynecology 15. National Association of Nurse Practitioners in Women's Health 16. Society of Family Planning 17. Society for Maternal-Fetal Medicine 18. Society of Gynecologic Oncology 19. Society of Gynecologic Surgeons 20. The Society of OB/GYN Hospitalists	

Dated: April 2, 2020 /s/ *Nicole A. Saharsky*

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INTEREST OF *AMICI CURIAE*

Amici are nationwide, non-partisan organizations of leading medical professionals and experts in the United States. They represent the doctors and nurses who are on the front lines caring for patients and fighting the COVID-19 pandemic. They file this brief because the Governor of Texas's new executive order, which according to the Attorney General effectively bans abortion in the state, poses a severe threat to the health and well-being of women in Texas. The executive order is contrary to the considered judgment of the medical community. If permitted to remain in effect, it will deny women essential medical care, care that should not be delayed or denied, in violation of the Constitution. A full list of *amici* is provided in the appendix to this brief.[1]

INTRODUCTION AND SUMMARY OF ARGUMENT

For the first time since 1973, abortion is effectively illegal in Texas. Physicians and medical professionals in the state face possible criminal prosecution if they provide this essential medical care. Reproductive health care is critical to a woman's overall health, and access to abortion

[1] No counsel for a party authored this brief in whole or in part, and no entity or person, other than *amici curiae*, their members, and their counsel, made a monetary contribution to the preparation or submission of this brief. *See* Fed. R. App. P. 29(a)(2), (a)(4)(E). The parties have consented to the filing of this brief.

is an important component of reproductive health care. *Amici* are leading societies of medical professionals, whose policies represent the considered judgment of many health care professionals in this country. *Amici*'s position is that laws that regulate abortion should be supported by a valid medical justification. The Governor's decision to effectively ban abortion in Texas during the COVID-19 pandemic lacks a valid medical justification. If allowed to remain in effect, the Governor's order will render abortion inaccessible in the state and will severely harm women.

On March 22, 2020, the Governor issued Executive Order GA-09, which bars "all surgeries and procedures that are not immediately medically necessary."[2] The order's stated purpose is to conserve hospital resources, including personal protective equipment (PPE).[3]

The Attorney General has interpreted the executive order to take the drastic step of banning all non-emergency abortions in Texas, and he

[2] Tex. Exec. Order No. GA-09, at 3 (Mar. 22, 2020), https://perma.cc/F6EU-EBPE.
[3] *Id.* (order exempts procedures that "would not deplete the hospital capacity or the personal protective equipment needed to cope with the COVID-19 disaster").

has stated he will criminally prosecute physicians and medical professionals who violate the order.[4] The ban is scheduled to last at least until April 21, 2020, or until the Governor modifies it.[5] The state defendants suggest that this is just a "three-week pause,"[6] but there is no medical or scientific reason to believe that the COVID-19 pandemic will be resolved in three weeks.

The executive order has the "force and effect of law."[7] Physicians and medical professionals who violate the law are subject to criminal penalties, including fines of up to $1,000 and imprisonment for up to 180 days.[8] Violators also are subject to administrative enforcement proceedings, which may result in discipline by the state medical board.[9]

This ban is contrary to the considered judgment of the country's leading physician organizations, including guidance from the American

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[4] Office of the Att'y Gen. of Tex., *Health Care Professionals and Facilities, Including Abortion Providers, Must Immediately Stop All Medically Unnecessary Surgeries and Procedures to Preserve Resources to Fight COVID-19 Pandemic* (Mar. 23, 2020) ("Those who violate the governor's order will be met with the full force of the law."), https://perma.cc/9WSX-JW6N.

[5] Tex. Exec. Order No. GA-09, at 3 (Mar. 22, 2020).

[6] Pet. for a Writ of Mandamus 2.

[7] Tex. Gov't Code Ann. § 418.012 (West 1987).

[8] *See* Tex. Gov't Code Ann. § 418.173 (West 1987).

[9] *See* 25 Tex. Admin. Code §§ 135.24(a)(1)(F), 139.32(b)(6); 22 Tex. Admin. Code § 185.17(11); Tex. Occ. Code Ann. §§ 164.051(a)(2)(B), (a)(6); 301.452(b)(3), (b)(10).

Medical Association, the American College of Obstetricians and Gynecologists, and the American College of Surgeons.[10] The Governor's ban on abortion in the state, except in cases of emergency, is not supported by accepted medical practice or scientific evidence. There is a broad medical consensus that abortion is essential health care, accessed by at least one-quarter of women in the United States during their lifetimes. There is no evidence that prohibiting abortion during the pandemic will mitigate PPE shortages or promote public health and safety.

The Governor's order will make safe abortion inaccessible in Texas. Abortion care will be delayed or, in some cases, denied altogether. Some women will travel long distances to go out of state to obtain abortion care. And some women likely will resort to unsafe methods of abortion.

There is no medical justification for this ban on abortion. *Amici's* members are on the front lines caring for patients, at great personal risk. They understand that the COVID-19 pandemic is a public health crisis

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[10] Am. Coll. of Obstetricians & Gynecologists (ACOG), *Joint Statement on Abortion Access During the COVID-19 Outbreak* (Mar. 18, 2020) (*ACOG Joint Statement*), https://perma.cc/52S9-LHUA; Am. Coll. of Surgeons, *COVID-19 Guidelines for Triage of Gynecology Patients* (Mar. 24, 2020) (*American College of Surgeons Statement*), https://perma.cc/4KXE-24KY; Am. Med. Ass'n, *AMA Statement on Government Interference in Reproductive Health Care* (Mar. 30, 2020) (*AMA Statement)*, https://perma.cc/2YZR-2UXT.

that requires the full attention and resources of our health care system. But the COVID-19 pandemic does not justify restricting abortion care in Texas. Most abortions do not require use of any hospital resources and use only minimal PPE. Indeed, the Governor's order is likely to *increase*, rather than decrease, burdens on hospitals and use of PPE. At the same time, it will severely impair essential health care for women, and it will place doctors, nurses, and other medical professionals in an untenable position by criminalizing necessary medical care.

The Court should deny the petition for a writ of mandamus.

ARGUMENT

I. ABORTION IS ESSENTIAL, TIME-SENSITIVE, AND SAFE HEALTH CARE

Abortion is an essential component of comprehensive health care. Like all medical matters, decisions regarding abortion should be made by patients in consultation with their physicians and health care professionals and without undue interference from outside parties.[11] The medical

[11] ACOG, *Statement of Policy, Abortion* (reaffirmed 2017) (*ACOG Abortion Policy*), https://perma.cc/73RA-RMUK.

community recognizes that "[a]ccess to legal and safe pregnancy termination . . . is essential to the public health of women everywhere."[12]

Abortion also is a common medical procedure. In 2017, medical professionals performed over 860,000 abortions nationwide,[13] including approximately 55,440 in Texas.[14] Approximately one-quarter of American women will have an abortion before the age of 45.[15]

Abortion is one of the safest medical procedures performed in the United States, and the vast majority of abortions are performed in outpatient non-hospital settings.[16] Complication rates from abortion are extremely low, and most complications are relatively minor and easily

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[12] Editors of the *New England Journal of Medicine* et al., *The Dangerous Threat to* Roe v. Wade, 381 New Eng. J. Med. 979, 979 (2019) (stating the view of the editors, along with several key organizations in obstetrics, gynecology, and maternal-fetal medicine, including the American Board of Obstetrics and Gynecology); *see ACOG Joint Statement*; *American College of Surgeons Statement; AMA Statement.*

[13] Rachel K. Jones et al., *Abortion Incidence and Service Availability in the United States, 2017*, at 7 (2019) (*Abortion Incidence 2017*).

[14] Guttmacher Inst., *State Facts About Abortion: Texas* (2020).

[15] Rachel K. Jones & Jenna Jerman, *Population Group Abortion Rates and Lifetime Incidence of Abortion: United States, 2008-2014*, 107 Am. J. Pub. Health 1904, 1908 (2017).

[16] *See, e.g.*, National Academies of Sciences, Engineering, Medicine, *The Safety and Quality of Abortion Care in the United States* 10 (2018) (*Safety and Quality of Abortion Care*) ("The clinical evidence clearly shows that legal abortions in the United States – whether by medication, aspiration, D&E, or induction – are safe and effective. Serious complications are rare.").

treatable.[17] The most common complications following an abortion typically can be treated by follow-up procedures at the clinic and/or with antibiotics.[18]

Major complications from abortion are exceptionally rare, occurring in just 0.23 to 0.50 percent of cases, depending on the method used.[19] The risk of death from abortion is even rarer. Nationally, fewer than one in 100,000 patients die from abortion-related complications.[20] The risk of death associated with childbirth is approximately fourteen times higher than the risk associated with abortion.[21]

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[17] Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175, 181 (2015) (Upadhyay); *see Safety and Quality of Abortion Care* 60.

[18] *See* ACOG, *Induced Abortion: What Complications Can Occur with an Abortion?* (2015), https://perma.cc/DFU5-WL5D; *Safety and Quality of Abortion Care* 116.

[19] Kari White et al., *Complications from First-Trimester Aspiration Abortion: A Systematic Review of the Literature*, 92 Contraception 422, 434, 435 tbl. 7 (2015) (White).

[20] Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States,* 119 Obstetrics & Gynecology 215, 216 (2012) (Raymond & Grimes); *see* ACOG, *Guidelines for Women's Health Care: A Resource Manual* 719 (4th ed. 2014).

[21] Raymond & Grimes 216.

Advances in medical science have expanded safe options for pregnancy termination. For example, medication abortion is a safe and effective option in the first trimester.[22] Thirty percent of abortions are medication abortions, where patients typically take the medication to complete the procedure at home.[23]

Non-medication abortion commonly is performed in clinics or doctor's offices, as opposed to hospitals. Nationally, 95 percent of abortions are performed in non-hospital settings.[24] There is no medically sound reason to assume that abortions performed in hospitals are safer than those performed in abortion clinics or offices. Indeed, scientific literature suggests that the safety of abortions performed in office settings is equivalent to those performed in hospital settings.[25]

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[22] *See Safety and Quality of Abortion Care* 10, 51-55.

[23] Tara C. Jatlaoui et al., *Abortion Surveillance – United States 2015*, 67 Morbidity & Mortality Weekly Rep. 1, 33 tbl. 11 (2018) (Jatlaoui); Rachel K. Jones & Jenna Jerman, *Abortion Incidence and Service Availability in the United States, 2014*, 49 Perspectives on Sexual & Reprod. Health 17, 24 tbl. 5 (2017) (*Abortion Incidence 2014*).

[24] Rachel K. Jones & Kathryn Kooistra, *Abortion Incidence and Access to Services in the United States, 2008*, 43 Perspectives on Sexual & Reprod. Health 41, 42 (2011) (*Abortion Incidence 2008*); Theodore Joyce, *The Supply-Side Economics of Abortion*, 365 New Eng. J. Med. 1466, 1467 (2011) (Joyce).

[25] Sarah C.M. Roberts, Ushma D. Upadhyay & Guodong Liu, *Association of Facility Type with Procedural-Related Morbidities and Adverse Events Among Patients Undergoing Induced Abortions*, 319 JAMA 2497, 2505 (2018); White 440; *see Safety and Quality of Abortion Care* 10, 73, 79.

The overwhelming weight of medical evidence conclusively demonstrates that abortion is an extremely safe, common medical procedure. The Supreme Court made just that point in *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016), when it noted that "[t]he great weight of evidence demonstrates that," before Texas enacted certain regulations, "abortion in Texas was extremely safe with particularly low rates of serious complications and virtually no deaths occurring on account of the procedure." *Id.* at 2302 (quoting district court's order). *See also June Medical Services LLC v. Kliebert*, 250 F. Supp. 3d 27, 61 (M.D. La. 2017) ("Abortion is one of the safest medical procedures in the United States."), *rev'd*, 905 F.3d 787 (5th Cir. 2018), *cert. granted*, 140 S. Ct. 35 (2019) (No. 18-1323) (argued Mar. 4, 2020).

While abortion is a safe and common medical procedure, it is also a time-sensitive one for which a delay may increase the risks or potentially make it completely inaccessible. The consequences of being unable to obtain an abortion profoundly impact a person's life, health, and well-being.

II. THE GOVERNOR'S ORDER WILL MAKE SAFE, LEGAL ABORTION INACCESSIBLE IN TEXAS

The Governor's order will lead to abortion care being delayed or denied. If Texas's abortion facilities must suspend all services while the executive order remains in effect, many patients seeking abortion care in early pregnancy will no longer be eligible for medication abortion.[26] Many patients may not be able to obtain care until the second trimester.[27] Second-trimester abortions "are more expensive, and fewer facilities offer the service."[28] And once the executive order expires, existing facilities may not have enough capacity to immediately provide abortion care to patients seeking that care, which will delay the service even further.[29]

Delays in obtaining an abortion can compromise patients' health. Abortion should be performed as early as possible because, although abortion procedures are among the safest medical procedures, the associated rate of complications increases as the pregnancy progresses.[30] The

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[26] Kari White et al., *The Potential Impacts of Texas' Executive Order on Patients' Access to Abortion Care* 1, Tex. Policy Evaluation Project, Research Brief (2020) (*Potential Impacts*), https://perma.cc/5V3F-25UK.

[27] *Id.*

[28] *Id.* at 2.

[29] *Id.*

[30] *Safety and Quality of Abortion Care* 75; *see ACOG Abortion Policy*.

chance of a major complication is higher in the second trimester than in the first trimester.[31]

As a result of the Governor's order, some women will travel out of state in order to attempt to obtain abortion care. One very recent study concluded that most women will have to travel large distances to obtain abortion care: "If Texas clinics are forced to suspend services while the executive order remains in effect, most counties (94%) will be 100 miles or more from a facility and approximately three-quarters (72%) will be over 200 miles away."[32] While the out-of-state travel itself poses an undue burden on women seeking abortion care, "most of Texas' neighboring states require a mandatory in-person consultation visit and 24-hour waiting period."[33] As a result, "many patients seeking care out of state would have to travel 800 round-trip miles or more to attend two separate visits."[34] While some patients may be able to stay overnight, "research indicates that fewer than one in five patients do so."[35] For many women,

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31 Upadhyay 181.
32 *Potential Impacts* 3.
33 *Id.*
34 *Id.*
35 *Id.*

especially low-income women, "[i]t is often difficult . . . to make the necessary arrangements to travel to a clinic, especially one that is far away. Finding child care, taking time off work and covering the cost of gas increase patients' out-of-pocket expenses and are logistically challenging to arrange."[36]

Out-of-state travel may be particularly challenging as a result of COVID-19 because of "economic uncertainty from lost wages and need to care for children who are at home."[37] Moreover, at least one bordering state – Oklahoma – has similarly attempted to outlaw abortion,[38] meaning that even women who would be able to travel to a state like Oklahoma could be unable to access care.

The Governor's order likely will cause some women to resort to unsafe methods of care. Studies have found that women are more likely to self-induce abortions when they face barriers to reproductive services.[39]

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[36] *Id.*

[37] *Id.*

[38] Okla. Fourth Am. Exec. Order 2020-07 (Mar. 24, 2020), https://perma.cc/A86V-2PMS; Office of Gov. J. Kevin Stitt, *Governor Stitt Clarifies Elective Surgeries and Procedures Suspended Under Executive Order* (Mar. 27, 2020), https://perma.cc/6V4H-YSMZ.

[39] *See, e.g.*, Lisa H. Harris & Daniel Grossman, *Complications of Unsafe and Self-Managed Abortion*, 382 New Eng. J. Med. 1029, 1029 (2020).

In Texas, many women will not have the means to travel out of state for abortion care, which increases the likelihood that they will attempt to self-induce abortion or seek an illegal abortion.[40] Methods of self-induction outside medical abortion may rely on harmful tactics such as herbal or homeopathic remedies, getting punched in the abdomen, using alcohol or illicit drugs, or taking hormonal pills.[41]

Previous experience in Texas proves the point: From 2011 to 2013, Texas severely curtailed the ability to obtain abortion care. In 2013, "the number of abortions performed in Texas declined 13% compared to the same period" the previous year, and "[t]he number of medication abortions provided . . . declined 70%."[42] A study that surveyed women seeking abortions revealed that "five of 23 respondents said they had thought about or looked into trying to self-manage their abortion; they said they did not pursue that option because they were worried that it

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[40] *See* ACOG, Comm. on Health Care for Underserved Women, *Opinion Number 613, Increasing Access to Abortion* 2-3 (2014) (*ACOG Opinion 613*); Elizabeth G. Raymond et al., *Mortality of Induced Abortion, Other Outpatient Surgical Procedures and Common Activities in the United States*, 90 Contraception 476, 478 (2014).

[41] Daniel Grossman et al., *Knowledge, Opinion and Experience Related to Abortion Self-Induction in Texas*, Tex. Policy Evaluation Project Research Brief 3 (2015).

[42] Liza Fuentes et al., *Texas Women's Decisions and Experiences Regarding Self-Managed Abortion*, BMC Women's Health 2 (2020).

would not be safe or that it would not be effective."[43] That study concluded that "self-managed abortion may become more common if clinic-based abortion care becomes more difficult to access, especially among women in south Texas" and "among poor women – who make up more than half of all abortion patients."[44]

Finally, evidence suggests that women are more likely to experience short-term psychological issues when denied an abortion. For example, women denied abortions because of gestational age bans are more likely to report short-term symptoms of anxiety than those women who received an abortion.[45] Accordingly, restrictions on abortion, such as those at issue here, are detrimental to women's physical and psychological health and well-being.

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[43] *Id.*

[44] *Id.* at 11.

[45] M. Antonia Biggs et al., *Women's Mental Health and Well-Being 5 Years After Receiving or Being Denied an Abortion: A Prospective, Longitudinal Cohort Study*, 74 JAMA Psychiatry 169, 172 (2017).

III. THERE IS NO MEDICAL JUSTIFICATION FOR THE GOVERNOR'S ORDER, AND IT WILL SEVERELY HARM WOMEN AND MEDICAL PROFESSIONALS

A. The COVID-19 Pandemic Does Not Justify Restricting Or Prohibiting Abortion Care In Texas

It is the consensus of the nation's medical experts that the COVID-19 pandemic does not justify restricting or prohibiting abortion care.[46] The vast majority of abortions are performed in non-hospital settings.[47] Very, very few abortions result in complications that require hospitalization.[48] Because most abortion care is delivered in outpatient settings, providing abortion care does not require hospital resources, including hospital PPE.

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[46] *ACOG Joint Statement* (ACOG and several other medical organizations "do not support COVID-19 responses that cancel or delay abortion procedures."); *American College of Surgeons Statement* (listing "[p]regnancy termination (for medical indication or patient request)" as a "[s]urger[y] that if significantly delayed could cause significant harm"); *AMA Statement* (In response to states issuing orders "ban[ning] or dramatically limit[ing] women's reproductive health care," the AMA's view is that "physicians – not politicians – should be the ones deciding which procedures are urgent-emergent and need to be performed, and which ones can wait, in partnership with our patients.").

[47] Jatlaoui 33 tbl. 11; Joyce 1467; *see Abortion Incidence 2014*, at 24 tbl. 5; *Abortion Incidence 2008*, at 42.

[48] Ushma D. Upadhyay et al., *Incidence of Post-Abortion Complications and Emergency Department Visits Among Nearly 55,000 Abortions Covered by the California Medi-Cal Program* slide 28 (Jan. 28, 2014) (ANSIRH Grand Rounds presentation), https://perma.cc/Y4NJ-WM7Q.

Permitting abortion care – which is essential, time-sensitive health care – will not substantially increase the burdens hospitals face as a result of the COVID-19 pandemic. In contrast, forcing women to carry pregnancies to term will increase reliance on the health care system and use of PPE. Pregnant women remain in the health care system. They often visit hospitals (including emergency rooms) for evaluation, thus using hospital bed space and resources. Most women give birth in hospitals and some births even require surgery. Further, women who attempt unsafe, unmanaged abortions may require emergency hospitalization, which could use significant hospital resources. Accordingly, the Governor's order will actually *increase* the burdens on hospitals and increase the use of PPE.

The Governor's order also is likely to increase, rather than decrease, the spread and severity of COVID-19. For the few women who may have the resources to travel to another state to obtain an abortion, there is no evidence that abortions in other states would utilize less medical equipment than abortions in Texas. Further, travel is one factor that

contributes to the spread of COVID-19.[49] Many Governors have issued "shelter-in-place" orders that prevent people from even leaving their homes, except in certain narrow circumstances, in order to reduce COVID-19 spread.[50]

To be sure, the availability of PPE is of critical importance to *amici,* who are on the front lines of the COVID-19 pandemic. *Amici*'s members are caring for patients every day in trying circumstances and in cases where they have not been provided adequate PPE or testing. Yet, it is disingenuous, at best, for the State to claim that banning abortion will preserve or mitigate shortages of PPE that the nation's medical professionals need to care for people during the pandemic. There is simply no evidence or logic under which that would be the case.

B. The Order Will Harm Women And Pose A Serious Threat To Medical Professionals In Texas

The Texas order bans all non-emergency abortions in the state, which will increase the likelihood that women will delay the procedure or will not be able to obtain the procedure at all. As discussed, the order

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[49] Centers for Disease Control & Prevention, *Coronavirus Disease 2019 (COVID-19) – Travel in the US* (last reviewed Mar. 30, 2020), https://perma.cc/2QA7-TL9M.

[50] *See* Sarah Mervosh et al., *See Which States and Cities Have Told Residents to Stay at Home*, N.Y. Times (updated Apr. 2, 2020), https://perma.cc/A6GF-HK7G.

means women may travel outside the state to obtain abortions, attempt to self-induce abortions through potentially harmful methods, or ultimately be unable to obtain abortions at all, forcing them to carry an unwanted pregnancy to term.[51] Each of these outcomes increases the likelihood of negative consequences to a woman's physical and psychological health that could be avoided if abortion services were available.[52] Being forced to carry a pregnancy to term could profoundly affect a person's life, health, and well-being.

The Governor's order also poses serious threats to physicians and medical professionals. Under the order, doctors, nurses, and other medical professionals who perform abortion care that is constitutionally protected and medically necessary could lose their licenses and even be subject to criminal penalties, including imprisonment.[53] Those are draconian sanctions to place on individuals who are only attempting to offer the best possible care to their patients.

* * * * *

[51] *See, e.g.*, *Abortion Incidence 2017*, at 3, 8.

[52] *See, e.g.*, *ACOG Opinion 613*.

[53] Tex. Exec. Order No. GA-09, at 3; *see* Tex. Gov't Code Ann. § 418.173 (West 1987); *see* 25 Tex. Admin. Code §§ 135.24(a)(1)(F), 139.32(b)(6); 22 Tex. Admin. Code § 185.17(11); Tex. Occ. Code Ann. §§ 164.051(a)(2)(B), (a)(6); 301.452(b)(3), (b)(10).

Abortion is essential health care for women, protected by the Constitution. For the first time since 1973, Texas has banned virtually all abortions in the state. No valid medical justification supports that ban. *Amici* urge this Court to deny the petition for a writ of mandamus.

CONCLUSION

For the foregoing reasons, the Court should deny the petition for a writ of mandamus.

Respectfully submitted,

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Dated: April 2, 2020

CERTIFICATE OF SERVICE

I hereby certify that on April 2, 2020, I electronically filed the foregoing brief with the Clerk of the Court using the appellate CM/ECF system. I further certify that all participants in this case are registered CM/ECF users and that service will be accomplished via CM/ECF.

Dated: April 2, 2020 /s/ *Nicole A. Saharsky*

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), the undersigned counsel for *Amici Curiae* certifies that this brief:

(i) complies with the type-volume limitation of Rule 29(a)(5) because it contains 3,800 words, including footnotes and excluding the parts of the brief exempted by Rule 32(f); and

(ii) complies with the typeface and type style requirements of Rule 32(a) and Fifth Circuit Rule 32.1 because it has been prepared using Microsoft Office Word 2016 and is set in Century Schoolbook font in a size equivalent to 14 points or larger.

Dated: April 2, 2020 /s/ *Nicole A. Saharsky*

APPENDIX

LIST OF *AMICI CURIAE*

1. The **American College of Obstetricians and Gynecologists** (ACOG) is the nation's leading group of physicians providing health care for women. With more than 60,000 members – representing more than 90 percent of all obstetricians-gynecologists in the United States – ACOG advocates for quality health care for women, maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of the changing issues facing women's health care. ACOG is committed to ensuring access to the full spectrum of evidence-based quality reproductive health care, including abortion care, for all women. ACOG opposes medically unnecessary laws or restrictions that serve to delay or prevent care. ACOG has previously appeared as *amicus curiae* in various courts throughout the country. ACOG's briefs and guidelines have been cited by numerous courts as providing authoritative medical data regarding childbirth and abortion.

2. The **American Medical Association** (AMA) is the largest professional association of physicians, residents, and medical students in

the United States. Additionally, through state and specialty medical societies and other physician groups seated in the AMA's House of Delegates, substantially all U.S. physicians, residents, and medical students are represented in the AMA's policymaking process. The objectives of the AMA are to promote the science and art of medicine and the betterment of public health. AMA members practice in all fields of medical specialization and in every state. The federal courts have cited the AMA's publications and *amicus curiae* briefs in cases implicating a variety of medical questions.

3. The **American Academy of Family Physicians** (AAFP) is the national medical specialty society representing family physicians. Founded in 1947 as a not-for-profit corporation, its 134,600 members are physicians and medical students from all 50 states, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, and the Uniformed Services of the United States. AAFP seeks to improve the health of patients, families, and communities by advocating for the health of the public and serving the needs of its members with professionalism and creativity.

4. The **American Academy of Nursing** (Academy) serves the public by advancing health policy through the generation, synthesis, and

dissemination of nursing knowledge. Academy Fellows are inducted into the organization for their extraordinary contributions to improve health locally and globally. With more than 2,800 Fellows, the Academy represents nursing's most accomplished leaders in policy, research, administration, practice, and academia.

5. The **American Academy of Pediatrics** (AAP) is a nonprofit professional organization founded in 1930 dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults. Its membership is comprised of 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. AAP has become a powerful voice for child and adolescent health through education, research, advocacy, and the provision of expert advice. AAP has worked with the federal and state governments, health care providers, and parents on behalf of America's families to ensure the availability of safe and effective reproductive health services.

6. **AAGL** is a professional medical association of 7,500 minimally invasive gynecologic surgeons and is the global leader in minimally invasive gynecologic surgery. AAGL's mission is to elevate the quality

and safety of health care for women through excellence in clinical practice, education, research, innovation and advocacy. AAGL is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

7. The **American College of Nurse-Midwives** (ACNM) works to advance the practice of midwifery to achieve optimal health for women through their lifespan, with expertise in women's health and gynecologic care. Its members include approximately 7,000 certified nurse midwives and certified midwives who provide primary and maternity care services to help women of all ages and their newborns attain, regain, and maintain health. ACNM and its members respect each woman's right to dominion over her own health and care, and ACNM advocates on behalf of women and families, its members, and the midwifery profession to eliminate health disparities and increase access to evidence-based, quality care.

8. The **American College of Osteopathic Obstetricians and Gynecologists** (ACOOG) is a non-profit, non-partisan organization committed to excellence in women's health representing over 2,500 providers. ACOOG educates and supports osteopathic physicians to improve the

quality of life for women by promoting programs that are innovative, visionary, inclusive, and socially relevant. ACOOG is likewise committed to the physical, emotional, and spiritual health of women.

9. The **American College of Physicians** (ACP) is the largest medical specialty organization in the U.S. and has members in more than 145 countries worldwide. ACP membership includes 159,000 internal medicine physicians, related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

10. The **American Osteopathic Association** (AOA) represents more than 151,000 osteopathic physicians (DOs) and osteopathic medical students; promotes public health; encourages scientific research; serves as the primary certifying body for DOs; and is the accrediting agency for osteopathic medical schools. As the primary certifying body for DOs and the accrediting agency for all osteopathic medical schools, the AOA works to accentuate the distinctiveness of osteopathic principles and the diversity of the profession.

11. The **American Psychiatric Association** (APA) is a non-profit organization representing over 38,800 physicians who specialize in the practice of psychiatry. APA members engage in research into and education about diagnosis and treatment of mental health and substance use disorders, and are front-line physicians treating patients who experience mental health and/or substance use disorders.

12. The **American Society of Reproductive Medicine** (ASRM) is a multidisciplinary not-for-profit organization dedicated to the advancement of the science and practice of reproductive medicine. Its members include approximately 8,000 professionals. ASRM accomplishes its mission through the pursuit of excellence in education and research and through advocacy on behalf of patients, physicians, and affiliated health care providers.

13. The **American Urogynecologic Society** (AUGS) is the premier non-profit organization representing professionals dedicated to treating female pelvic floor disorders. Founded in 1979, AUGS represents more than 1,900 members, including practicing physicians, nurse practitioners, physical therapists, nurses and health care professionals, and researchers from many disciplines.

14. The **North American Society for Pediatric and Adolescent Gynecology** (NASPAG) is dedicated to providing multidisciplinary leadership in education, research, and gynecologic care to improve the reproductive health of youth. NASPAG conducts and encourages multidisciplinary and inter-professional programs of medical education and research in the field and advocates for the reproductive well-being of children and adolescents and the provision of unrestricted, unbiased, and evidence-based medical practice.

15. The **National Association of Nurse Practitioners in Women's Health** (NPWH) is a national non-profit educational and professional organization that works to ensure the provision of quality primary and specialty health care to women of all ages by women's health and women's health focused nurse practitioners. Its mission includes protecting and promoting a woman's right to make her own choices regarding her health within the context of her personal, religious, cultural, and family beliefs. Since its inception in 1980, NPWH has been a trusted source of information on nurse practitioner education, practice, and women's health issues. In keeping with its mission, NPWH is committed

to ensuring the availability of the full spectrum of evidence-based reproductive health care for women and opposes unnecessary restrictions on access that serve to delay or prevent care.

16. The **Society of Family Planning** (SFP) is the source for science on abortion and contraception. SFP represents approximately 800 scholars and academic clinicians united by a shared interest in advancing the science and clinical care of family planning. The pillars of its strategic plan are (1) building and supporting a multidisciplinary community of scholars and partners who have a shared focused on the science and clinical care of family planning; (2) supporting the production of research primed for impact; (3) advancing the delivery of clinical care based on the best available evidence; and (4) driving the uptake of family planning evidence into policy and practice.

17. The **Society for Maternal-Fetal Medicine** (SMFM), founded in 1977, is the medical professional society for obstetricians who have additional training in the area of high-risk, complicated pregnancies. Representing over 4,000 members, SMFM supports the clinical practice of maternal-fetal medicine by providing education, promoting research, and engaging in advocacy to reduce disparities and optimize the

health of high-risk pregnant women and their babies. SMFM and its members are dedicated to ensuring that medically appropriate treatment options are available for high-risk women.

18. The **Society of Gynecologic Oncology** (SGO) is the premier medical specialty society for health care professionals trained in the comprehensive management of gynecologic cancers. With 2,000 members representing the entire gynecologic oncology team in the United States and abroad, the SGO contributes to the advancement of women's cancer care by encouraging research, providing education, raising standards of practice, advocating for patients and members and collaborating with other domestic and international organizations. In that mission, the SGO strives to ensure access to women's health care as part of an overall prevention strategy for gynecologic cancer.

19. The mission of the **Society of Gynecologic Surgeons** is to promote excellence in gynecologic surgery through acquisition of knowledge and improvement of skills, advancement of basic and clinical research, and professional and public education.

20. The **Society of OB/GYN Hospitalists** (SOGH) is a rapidly growing group of physicians, midwives, nurses and other individuals in

the health care field who support the OB/GYN Hospitalist model. SOGH is dedicated to improving outcomes for hospitalist women and supporting those who share this mission. SOGH's vision is to shape the future of OB/GYN by establishing the hospitalist model as the care standard and the Society values excellence, collaboration, leadership, quality and community.

Exhibit 1-4

The Safety and Quality of Abortion Care in the United States

Committee on Reproductive Health Services:
Assessing the Safety and Quality of Abortion Care in the U.S.

Board on Population Health and Public Health Practice

Board on Health Care Services

Health and Medicine Division

A Consensus Study Report of

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

THE NATIONAL ACADEMIES PRESS
Washington, DC
www.nap.edu

Contents

Summary[1]

When the Institute of Medicine (IOM)[2] issued its 1975 report on the public health impact of legalized abortion, the scientific evidence on the safety and health effects of legal abortion services was limited. It had been only 2 years since the landmark *Roe v. Wade* decision had legalized abortion throughout the United States, and nationwide data collection was just under way. Today, the available evidence on abortion's health effects is quite robust. There is a great deal of related scientific research, including well-designed randomized controlled trials, systematic reviews, and epidemiological studies examining the relative safety of abortion methods and the appropriateness of methods for different clinical circumstances. With this growing body of research, medical and surgical abortion methods have been refined or discontinued, and new techniques have been developed.

In 2016, six private foundations came together to ask the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine to conduct a comprehensive review of the state of the science on the safety and quality of legal abortion services in the United States. The sponsors—The David and Lucile Packard Foundation, The Grove Foundation, The JPB Foundation, The Susan Thompson Buffett Foundation, Tara Health Foundation, and William and Flora Hewlett Foundation—asked

[1]This summary does not include references. Relevant citations appear in subsequent chapters.

[2]In March 2016, the division of the National Academies of Sciences, Engineering, and Medicine that focuses on health and medicine, previously known as the Institute of Medicine (IOM), was renamed the Health and Medicine Division.

Mental health effects The committee identified a wide array of research on whether abortion increases women's risk of depression, anxiety, and/or posttraumatic stress disorder and concludes that having an abortion does not increase a woman's risk of these mental health disorders.

3. What is the evidence on the safety and quality of medical and surgical abortion care?

Safety The clinical evidence clearly shows that legal abortions in the United States—whether by medication, aspiration, D&E, or induction—are safe and effective. Serious complications are rare. But the risk of a serious complication increases with weeks' gestation. As the number of weeks increases, the invasiveness of the required procedure and the need for deeper levels of sedation also increase.

Quality Health care quality is a multidimensional concept. As noted above, six attributes of health care quality—safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity—were central to the committee's review of the quality of abortion care. Table S-1 details the committee's conclusions regarding each of these quality attributes. Overall, the committee concludes that the quality of abortion care depends to a great extent on where women live. In many parts of the country, state regulations have created barriers to optimizing each dimension of quality care. The quality of care is optimal when the care is based on current evidence and when trained clinicians are available to provide abortion services.

4. What is the evidence on the minimum characteristics of clinical facilities necessary to effectively and safely provide the different types of abortion interventions?

Most abortions can be provided safely in office-based settings. No special equipment or emergency arrangements are required for medication abortions. For other abortion methods, the minimum facility characteristics depend on the level of sedation that is used. Aspiration abortions are performed safely in office and clinic settings. If moderate sedation is used, the facility should have emergency resuscitation equipment and an emergency transfer plan, as well as equipment to monitor oxygen saturation, heart rate, and blood pressure. For D&Es that involve deep sedation or general anesthesia, the facility should be similarly equipped and also have equipment to provide general anesthesia and monitor ventilation.

Women with severe systemic disease require special measures if they desire or need deep sedation or general anesthesia. These women require

TABLE S-1 Does Abortion Care in the United States Meet the Six Attributes of Quality Health Care?

Quality Attribute[a]	Definition	Committee's Conclusions
Safety	Avoiding injuries to patients from the care that is intended to help them.	Legal abortions—whether by medication, aspiration, D&E, or induction—are safe. Serious complications are rare and occur far less frequently than during childbirth. Safety is enhanced when the abortion is performed as early in pregnancy as possible.
Effectiveness[b]	Providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively).	Legal abortions—whether by medication, aspiration, D&E, or induction—are effective. The likelihood that women will receive the type of abortion services that best meet their needs varies considerably depending on where they live. In many parts of the country, abortion-specific regulations on the site and nature of care, provider type, provider training, and public funding diminish this dimension of quality care. The regulations may limit the number of available providers, misinform women of the risks of the procedures they are considering, overrule women's and clinician's medical decision making, or require medically unnecessary services and delays in care. These include policies that • require office-based settings to meet the structural standards of higher-intensity clinical facilities (e.g., ambulatory surgery centers or hospitals) even for the least invasive abortion methods (medication and aspiration); • prohibit the abortion method that is most effective for a particular clinical circumstance (e.g., D&E); • delay care unnecessarily from a clinical standpoint (e.g., mandatory waiting periods); • prohibit qualified clinicians (family medicine physicians, certified nurse-midwives, nurse practitioners, and physician assistants) from performing abortions; • require the informed consent process to include inaccurate information on abortion's long-term physical and mental health effects; • require individual clinicians to have hospital privileges; • bar publicly funded clinics from providing abortion care to low-income women; or • mandate clinically unnecessary services (e.g., preabortion ultrasound, in-person counseling visit).

continued

the clinician needs the relevant surgical expertise and sufficient caseload to maintain the requisite surgical skills. To provide induction abortions, the clinician requires the skills needed for managing labor and delivery.

Clinicians that have the necessary competencies Both trained physicians (OB/GYNs, family medicine physicians, and other physicians) and APCs (physician assistants, certified nurse-midwives, and nurse practitioners) can provide medication and aspiration abortions safely and effectively. OB/GYNs, family medicine physicians, and other physicians with appropriate training and experience can provide D&E abortions. Induction abortions can be provided by clinicians (OB/GYNs, family medicine physicians, and certified nurse-midwives) with training in managing labor and delivery.

The extensive body of research documenting the safety of abortion care in the United States reflects the outcomes of abortions provided by thousands of individual clinicians. The use of sedation and anesthesia may require special expertise. If moderate sedation is used, it is essential to have a nurse or other qualified clinical staff—in addition to the person performing the abortion—available to monitor the patient, as is the case for any other medical procedure. Deep sedation and general anesthesia require the expertise of an anesthesiologist or certified registered nurse anesthetist to ensure patient safety.

6. *What safeguards are necessary to manage medical emergencies arising from abortion interventions?*

The key safeguards—for abortions and all outpatient procedures—are whether the facility has the appropriate equipment, personnel, and emergency transfer plan to address any complications that might occur. No special equipment or emergency arrangements are required for medication abortions; however, clinics should provide a 24-hour clinician-staffed telephone line and have a plan to provide emergency care to patients after hours. If moderate sedation is used during an aspiration abortion, the facility should have emergency resuscitation equipment and an emergency transfer plan, as well as equipment to monitor oxygen saturation, heart rate, and blood pressure. D&Es that involve deep sedation or general anesthesia should be provided in similarly equipped facilities that also have equipment to monitor ventilation.

The committee found no evidence indicating that clinicians that perform abortions require hospital privileges to ensure a safe outcome for the patient. Providers should, however, be able to provide or arrange for patient access or transfer to medical facilities equipped to provide blood transfusions, surgical intervention, and resuscitation, if necessary.

1

Introduction

When the Institute of Medicine (IOM)[1] issued its 1975 report on the public health impact of legalized abortion, the scientific evidence on the safety and health effects of legal abortion services was limited (IOM, 1975). It had been only 2 years since the landmark *Roe v. Wade* decision had legalized abortion throughout the United States and nationwide data collection was just under way (Cates et al., 2000; Kahn et al., 1971). Today, the available scientific evidence on abortion's health effects is quite robust.

In 2016, six private foundations came together to ask the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine to conduct a comprehensive review of the state of the science on the safety and quality of legal abortion services in the United States. The sponsors—The David and Lucile Packard Foundation, The Grove Foundation, The JPB Foundation, The Susan Thompson Buffett Foundation, Tara Health Foundation, and William and Flora Hewlett Foundation—asked that the review focus on the eight research questions listed in Box 1-1.

The Committee on Reproductive Health Services: Assessing the Safety and Quality of Abortion Care in the U.S. was appointed in December 2016 to conduct the study and prepare this report. The committee included 13 individuals[2] with research or clinical experience in anesthesiology,

[1]In March 2016, the IOM, the division of the National Academies of Sciences, Engineering, and Medicine focused on health and medicine, was renamed the Health and Medicine Division.

[2]A 14th committee member participated for just the first 4 months of the study.

is, the successful completion of an abortion without the need for a follow-up aspiration.

Finding and Assessing the Evidence

The committee deliberated during four in-person meetings and numerous teleconferences between January 2017 and December 2017. On March 24, 2017, the committee hosted a public workshop at the Keck Center of the National Academies of Sciences, Engineering, and Medicine in Washington, DC. The workshop included presentations from three speakers on topics related to facility standards and the safety of outpatient procedures. Appendix C contains the workshop agenda.

Several committee workgroups were formed to find and assess the quality of the available evidence and to draft summary materials for the full committee's review. The workgroups conducted in-depth reviews of the epidemiology of abortions, including rates of complications and mortality, the safety and effectiveness of alternative abortion methods, professional standards and methods for performing all aspects of abortion care (as described in Figure 1-1), the short- and long-term physical and mental health effects of having an abortion; and the safety and quality implications of abortion-specific regulations on abortion.

The committee focused on finding reliable, scientific information reflecting contemporary U.S. abortion practices. An extensive body of research on abortion has been conducted outside the United States. A substantial proportion of this literature concerns the delivery of abortion care in countries where socioeconomic conditions, culture, population health, health care resources, and/or the health care system are markedly different from their U.S. counterparts. Studies from other countries were excluded from this review if the committee judged those factors to be relevant to the health outcomes being assessed.

The committee considered evidence from randomized controlled trials comparing two or more approaches to abortion care; systematic reviews; meta-analyses; retrospective cohort studies, case control studies, and other types of observational studies; and patient and provider surveys (see Box 1-4).

An extensive literature documents the biases common in published research on the effectiveness of health care services (Altman et al., 2001; Glasziou et al., 2008; Hopewell et al., 2008; Ioannidis et al., 2004; IOM, 2011a,b; Plint et al., 2006; Sackett, 1979; von Elm et al., 2007). Thus, the committee prioritized the available research according to conventional principles of evidence-based medicine intended to reduce the risk of bias in a study's conclusions, such as how subjects were allocated to different types of abortion care, the comparability of study populations, controls

highly effective at determining eligibility for medication abortion—patients accurately assessed their eligibility (Bracken et al., 2011).

SAFETY AND EFFECTIVENESS OF CURRENT ABORTION METHODS

Several methods—medication, aspiration, dilation and evacuation (D&E), and induction—are used to perform an abortion depending on weeks' gestation, patient preference, provider skill, need and desire for sedation, costs, clinical setting, and state policies and regulations.

Medication Abortion

Medication abortion in early pregnancy is accomplished using mifepristone, a progesterone receptor antagonist that competitively interacts with progesterone at the progesterone receptor site, thereby inhibiting the activity of endogenous or exogenous progesterone. This process initiates the breakdown of the endometrium and implanted embryo (Borkowski et al., 2015). Mifepristone, sold under the brand name Mifeprex,[1] is the only medication specifically approved by the FDA for use in medication abortion (Woodcock, 2016). Taken orally, it has been shown to increase sensitivity to prostaglandins and is most commonly used in conjunction with misoprostol, a prostaglandin E1 analogue. Misoprostol causes uterine contractions as well as cervical ripening and can be administered orally, sublingually, buccally, or vaginally.[2] Since mifepristone's initial FDA approval in 2000, an extensive body of research has led to improvements in the drug's protocol, including a lower recommended dosage, an increased period of eligibility from 49 days' to 70 days' (10 weeks') gestation, and a recommendation that the misoprostol be taken buccally rather than sublingually or orally to minimize side effects (Borkowski et al., 2015; Chai et al., 2013). The World Health Organization (WHO) has included mifepristone and misoprostol on its Model List of Essential Medicines since 2005 (WHO, 2015).[3]

Few women have contraindications to medication abortion (ACOG and SFP, 2014). The FDA-approved Mifeprex label states that the drug should not be used for women with confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass; an IUD in place; chronic adrenal

[1]Mifeprex is manufactured and distributed by Danco Laboratories. Danco is the only distributer of Mifeprex in the United States.

[2]A sublingual medication is dissolved under the tongue. Buccal medications are placed between the gums and the cheek.

[3]Where permitted under national law and where culturally acceptable (WHO, 2015).

complications in women with Class III obesity was significant (OR = 5.04; 95% CI = 1.65–15.39).

Hemorrhage In studies of abortions performed in the year 2000 or later, D&E-related hemorrhage requiring transfusion or other treatment occurred in 0.0 to 1.0 percent of cases (Frick et al., 2010; Grossman et al., 2011a; Mauelshagen et al., 2009).

Infection Routine antibiotic prophylaxis is recommended for all surgical abortions (ACOG, 2013; NAF, 2017a; RCOG, 2015; WHO, 2014). Infection after a D&E is uncommon, with rates ranging from 0.0 to 2.0 percent (Autry et al., 2002; Grossman et al., 2011a; Mauelshagen et al., 2009). In the California Medicaid study described above, Upadhyay and colleagues (2015) found that 0.3 percent or 18 of 8,837 abortions performed after 13 weeks' gestation resulted in an infection, although these procedures included both D&Es and inductions.

Cervical lacerations Injuries to the cervix and uterus have decreased significantly with routine cervical preparation prior to D&E (ACOG, 2013). Recent studies have reported rates of 0.02 to 3.3 percent (Autry et al., 2002; Frick et al., 2010). The risk of cervical laceration is associated with mechanical dilation, nulliparity, advanced gestation, and provider inexperience (ACOG, 2013). Thus, as noted above, performing D&E procedures requires advanced training and/or experience.

Uterine perforation While uterine perforation is more common in D&E than in aspiration procedures, the incidence remains quite low and is likely related to the availability of cervical preparation and ultrasound guidance (Grossman et al., 2008). Limited clinician experience and underestimation of the duration of pregnancy are also factors that have been associated with uterine perforation (Grossman et al., 2008). A 1989 study compared the incidence of perforation during 810 D&E procedures with and without sonography (Darney and Sweet, 1989). Using ultrasound to guide the use of intrauterine forceps clearly improved the safety of the procedure: the rate of perforation declined significantly from 1.4 to 0.2 percent. Studies dating from 2010 to 2015 report perforation rates ranging from 0.2 to 0.8 percent (Frick et al., 2010; Upadhyay et al., 2015).

The facility requirements that are appropriate for D&Es depend on the level of sedation and anesthesia that is used. (See later in this chapter for a review of the use of analgesia, sedation, and anesthesia during abortions.)

(without intubation) in a high-volume licensed clinic in New York State between 2001 and 2008.[20] Deep sedation was provided only to medically eligible patients who followed strict fasting guidelines. The procedures were monitored by an anesthesiologist or CRNA. The researchers reviewed the medical records of all women who were transferred to a hospital (n = 26) because of complications and found that no hospital transfers occurred because of an anesthesia complication.

In a more recent study, Gokhale and colleagues (2016) assessed the outcomes for 5,579 aspiration and D&E abortions using IV sedation (without intubation) at a freestanding abortion clinic in Cleveland from 2012 to 2013. Patients were screened for medical eligibility and followed fasting guidelines. Sedation was administered by registered nurses or by CRNAs if propofol was administered. There were no hospital transfers for anesthesia-related indications. Naloxone was required for opioid reversal in 0.2 percent of patients. The study also compared outcomes for obese and nonobese women; no differences were found.

Induction Pain Management

There is little research on how best to manage pain during an induction (Jackson and Kapp, 2011). Comparisons of different analgesic regimens are not available, and the optimal approach to effective treatment of pain is not well established (Wiebe and Renner, 2014). The options will depend on the provider's resources and the particular clinical circumstances. Nulliparous women may require more analgesia compared with multiparous women (Ashok et al., 2004). The levels of pain in later-gestation induction abortions are said to be similar to those in normal delivery, but the committee found no studies documenting this (Smith et al., 2016; Viviand et al., 2003).

MORTALITY

Death associated with a legal abortion in the United States is an exceedingly rare event. As Table 2-4 shows, the risk of death subsequent to a legal abortion[21] (0.7 per 100,000) is a small fraction of that for childbirth (8.8 per 100,000) (Bartlett et al., 2004; Zane et al., 2015).[22] Abortion-related

[20]One patient received an endotracheal intubation.

[21]The CDC defines an abortion-related death as "a death resulting from a direct complication of an induced abortion, an indirect complication caused by a chain of events initiated by an abortion procedure, or the aggravation of a pre-existing condition by the physiologic or psychological effects of the abortion" (Jatlaoui et al., 2016, p. 4).

[22]The CDC calculates the rate of abortion mortality using deaths reported to the CDC Abortion Surveillance System and dividing them by the estimated number of abortion procedures in the United States (CDC, 2017; Jones and Jerman, 2014).

TABLE 2-4 Comparison of Mortality Rates for Abortion, Childbirth, Colonoscopy, Dental Procedures, Plastic Surgery, and Tonsillectomy, United States

Procedure (Study Period)	Mortality Rate (number of deaths per 100,000 procedures)
Abortion (legal) (1988–2010)	0.7
Childbirth (1988–2005)	8.8
Colonoscopy (2001–2015)	2.9
Dental procedures (1999–2005)	0.0 to 1.7
Plastic surgery (2000–2012)	0.8 to 1.7
Tonsillectomy (1968–1972)	2.9 to 6.3

NOTE: Reported tonsillectomy rates were recalculated to reflect the rate per 100,000 procedures.
SOURCES: Baugh et al., 2011; Raymond and Grimes, 2012; Raymond et al., 2014; Reumkens et al., 2016; Zane et al., 2015.

mortality is also lower than that for colonoscopies (2.9 per 100,000), plastic surgery (0.8 to 1.7 per 100,000), dental procedures (0.0 to 1.7 per 100,000), and adult tonsillectomies (2.9 to 6.3 per 100,000). Comparable data for other common medical procedures are difficult to find.

The CDC monitors abortion-related deaths through its Pregnancy Mortality Surveillance System (Jatlaoui et al., 2017). The surveillance data underscore the increased risk of having an abortion later in pregnancy. Zane and colleagues (2015) assessed differences in abortion-related mortality by race, maternal age, and weeks' gestation using data from the CDC surveillance system. Among the 16.1 million legal abortions performed from 1998 to 2010, there were 108 deaths (0.7 per 100,000). Twenty deaths occurred among high-risk women whose pregnancy was life threatening. Infection and anesthesia complications were the most frequent cause of death for procedures performed up to 13 weeks' gestation. After 13 weeks, the deaths reported were due primarily to infection or hemorrhage.

The researchers found that weeks' gestation was the strongest predictor of abortion-related mortality. At 8 weeks' gestation or less, the death rate was 0.3 per 100,000; after 17 weeks, the rate was 6.7 per 100,000. Death rates were approximately three times as high for black women as for white women—similar to the disparities found in pregnancy outcomes overall (Creanga et al., 2012, 2015, 2017; MacDorman et al., 2017). From 2011 to 2013, for example, the overall maternal mortality ratio for non-Hispanic black women was 3.4 times higher than that for non-Hispanic white women (Creanga et al., 2017). A study of maternal mortality in 2013 to 2014 found a 22 percent lower ($p = .02$) mortality rate for Hispanic women compared with non-Hispanic white women; in 2008–2009, the

(e.g., qualified advanced practice clinicians [APCs] or physicians without hospital privileges may be barred from performing abortions); how the informed consent process is conducted (e.g., providers may be required to misrepresent the risks of the procedure); the abortion method that is used (e.g., D&Es may be banned); the timing and scheduling of procedures (e.g., women may have to wait 18 to 72 hours after a counseling appointment); the physical attributes of the clinical setting (e.g., procedure room size, corridor width); and other basic elements of care. In most states, the regulations apply to all abortion methods regardless of weeks' gestation, use of sedation, or the invasiveness of the procedure.

See Table 1-1 in Chapter 1 for a listing of abortion-specific regulations by states as of September 1, 2017.

SUMMARY

The clinical evidence presented in this chapter on the provision of safe and high-quality abortion care stands in contrast to the extensive regulatory requirements that state laws impose on the provision of abortion services. These requirements may influence the efficiency of abortion care by requiring medically unnecessary services and multiple visits to the abortion facility, in addition to requiring that care take place in costlier and more sophisticated settings than are clinically necessary. These requirements go beyond the accepted standards of care in the absence of evidence that they improve safety. Some requirements, such as multiple visits and waiting periods, delay abortion services, and by doing so may increase the clinical risks and cost of care. They may also limit women's options for care and impact providers' ability to provide patient-centered care. Furthermore, many of these laws have been documented to reduce the availability of care by imposing unneeded regulations on abortion providers and the settings in which abortion services are delivered. The implications of abortion-specific regulations for the safety and quality of abortion care are described below.

Delaying the Procedure

The clinical evidence makes clear that legal abortions in the United States—whether by medication, aspiration, D&E, or induction—are safe and effective. Serious complications are rare; in the vast majority of studies, they occur in fewer than 1 percent of abortions, and they do not exceed 5 percent in any of the studies the committee identified. However, the risk of a serious complication increases with weeks' gestation. As the number of weeks increases, the invasiveness of the required procedure and the need for

deeper levels of sedation also increase. Thus, delaying the abortion increases the risk of harm to the woman.

State regulations that require women to make multiple in-person visits and wait multiple days delay the abortion. If the waiting period is required *after* an in-person counseling appointment, the delay is exacerbated (Roberts et al., 2016; Sanders et al., 2016; White et al., 2017). Restrictions on the types of providers and on the settings in which abortion services can be provided also delay care by reducing the availability of care (Baum et al., 2016; Fuentes et al., 2016; Gerdts et al., 2016; Grossman et al., 2014, 2017).

Financial burdens and difficulty obtaining insurance are frequently cited by women as reasons for delay in obtaining an abortion (Bessett et al., 2011; Drey et al., 2006; Finer et al. 2006; Foster and Kimport, 2013; Foster et al., 2008; French et al., 2016; Janiak et al., 2014; Kiley et al., 2010; Roberts et al., 2014; Upadhyay et al., 2014). As noted in Chapter 1, 33 states prohibit public payers from paying for abortions, and other states have laws that either prohibit health insurance exchange plans (25 states) or private insurance plans (11 states) sold in the state from covering or paying for abortions, with few exceptions.[26]

Counseling and Informed Consent

Long-established ethical and legal standards for informed consent in health care appear to have been compromised in the delivery of abortion care in many areas of the country. Thirty-five states have abortion-specific regulations requiring women to receive counseling before an abortion is performed, and abortion patients in many of these states are offered or given inaccurate or misleading information (verbally or in writing) on reversing medication abortions, risks to future fertility, possible breast cancer risk, and/or long-term mental health consequences of abortion (Guttmacher Institute, 2017a) (see Table 1-1 in Chapter 1). As noted earlier in this chapter, the principal objective of the informed consent process is that patients understand the nature and risks of the procedure they are considering (AAAHC, 2016; AMA, 2016; HHS, 2017a; Joint Commission, 2016). However, legally requiring providers to inform women about risks that are not supported and are even invalidated by scientific research violates the accepted standards of informed consent. For example, some states require that providers inform women that abortion puts them at greater risk for breast cancer; mental health disorders; and difficulties in having a healthy, successful pregnancy

[26]Exceptions are limited and vary by state. They are often made for pregnancies resulting from rape or incest, pregnancies that endanger the woman's life or severely threaten the health of the woman, and cases of fetal impairment.

safe and effective. Serious complications are rare. But the risk of a serious complication increases with weeks' gestation. As the number of weeks increases, the invasiveness of the required procedure and the need for deeper levels of sedation also increase.

Quality Health care quality is a multidimensional concept. Six attributes of health care quality—safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity—were central to the committee's review of the quality of abortion care. Table 5-1 details the committee's conclusions regarding each of these quality attributes. Overall, the committee concludes that the quality of abortion care depends to a great extent on where women live. In many parts of the country, state regulations have created barriers to optimizing each dimension of quality care. The quality of care is optimal when the care is based on current evidence and when trained clinicians are available to provide abortion services.

4. ***What is the evidence on the minimum characteristics of clinical facilities necessary to effectively and safely provide the different types of abortion interventions?***

Most abortions can be provided safely in office-based settings. No special equipment or emergency arrangements are required for medication abortions. For other abortion methods, the minimum facility characteristics depend on the level of sedation that is used. Aspiration abortions are performed safely in office and clinic settings. If moderate sedation is used, the facility should have emergency resuscitation equipment and an emergency transfer plan, as well as equipment to monitor oxygen saturation, heart rate, and blood pressure. For D&Es that involve deep sedation or general anesthesia, the facility should be similarly equipped and also have equipment to provide general anesthesia and monitor ventilation.

Women with severe systemic disease require special measures if they desire or need deep sedation or general anesthesia. These women require further clinical assessment and should have their abortion in an accredited ambulatory surgery center or hospital.

5. ***What is the evidence on what clinical skills are necessary for health care providers to safely perform the various components of abortion care, including pregnancy determination, counseling, gestational age assessment, medication dispensing, procedure performance, patient monitoring, and follow-up assessment and care?***

Required skills All abortion procedures require competent providers skilled in patient preparation (education, counseling, and informed consent);

TABLE 5-1 Does Abortion Care in the United States Meet the Six Attributes of Quality Health Care?

Quality Attribute[a]	Definition	Committee's Conclusions
Safety	Avoiding injuries to patients from the care that is intended to help them.	Legal abortions—whether by medication, aspiration, D&E, or induction—are safe. Serious complications are rare and occur far less frequently than during childbirth. Safety is enhanced when the abortion is performed as early in pregnancy as possible.
Effectiveness[b]	Providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively).	Legal abortions—whether by medication, aspiration, D&E, or induction—are effective. The likelihood that women will receive the type of abortion services that best meets their needs varies considerably depending on where they live. In many parts of the country, abortion-specific regulations on the site and nature of care, provider type, provider training, and public funding diminish this dimension of quality care. The regulations may limit the number of available providers, misinform women of the risks of the procedures they are considering, overrule women's and clinician's medical decision making, or require medically unnecessary services and delays in care. These include policies that • require office-based settings to meet the structural standards of higher-intensity clinical facilities (e.g., ambulatory surgery centers or hospitals) even for the least invasive abortion methods (medication and aspiration); • prohibit the abortion method that is most effective for a particular clinical circumstance (e.g., D&E); • delay care unnecessarily from a clinical standpoint (e.g., mandatory waiting periods); • prohibit qualified clinicians (family medicine physicians, certified nurse-midwives, nurse practitioners, and physician assistants) from performing abortions; • require the informed consent process to include inaccurate information on abortion's long-term physical and mental health effects; • require individual clinicians to have hospital privileges; • bar publicly funded clinics from providing abortion care to low-income women; or • mandate clinically unnecessary services (e.g., preabortion ultrasound, in-person counseling visit).

continued

Exhibit 1-5

ACOG
The American College of Obstetricians and Gynecologists

Clinical | Mar 18, 2020

Joint Statement on Abortion Access During the COVID-19 Outbreak

The American College of Obstetricians and Gynecologists and the American Board of Obstetrics & Gynecology, together with the American Association of Gynecologic Laparoscopists, the American Gynecological & Obstetrical Society, the American Society for Reproductive Medicine, the Society for Academic Specialists in General Obstetrics and Gynecology, the Society of Family Planning, and the Society for Maternal-Fetal Medicine, released the following statement:

“As hospital systems, clinics, and communities prepare to meet anticipated increases in demand for the care of people with COVID-19, strategies to mitigate spread of the virus and to maximize health care resources are evolving. Some health systems, at the guidance of the CDC, are implementing plans to cancel elective and non-urgent procedures to expand hospitals’ capacity to provide critical care.

“While most abortion care is delivered in outpatient settings, in some cases care may be delivered in hospital-based settings or surgical facilities. To the extent that hospital systems or ambulatory surgical facilities are categorizing procedures that can be delayed during the COVID-19 pandemic, abortion should not be categorized as such a procedure. Abortion is an essential component of comprehensive health care. It is also a time-sensitive service for which a delay of several weeks, or in some cases days, may increase the risks or potentially make it completely inaccessible. The consequences of being unable to obtain an abortion profoundly impact a person’s life, health, and well-being.

“The American College of Obstetricians and Gynecologists and the American Board of Obstetrics & Gynecology, together with the American Association of Gynecologic Laparoscopists, the American Gynecological & Obstetrical Society, the American Society for Reproductive Medicine, the Society for Academic Specialists in General Obstetrics and Gynecology, the Society of Family Planning, and

the Society for Maternal-Fetal Medicine, do not support COVID-19 responses that cancel or delay abortion procedures. Community-based and hospital-based clinicians should consider collaboration to ensure abortion access is not compromised during this time."

Topics **Coronavirus** **COVID-19** **Delivery of health care** **Health services accessibility** **Induced abortion** **Medical societies** **Obstetric surgical procedures** **Organizations** **Virus diseases** **Women's health services**

Latest Clinical News

ACOG Releases Updated Guidance on Exercise in Pregnancy and Postpartum, Includes Recommendations for Athletes

Mar 26, 2020

Joint Statement on Elective Surgeries

Mar 16, 2020

ACOG Updates on Novel Coronavirus Disease 2019 (COVID-19)

Mar 6, 2020

ACOG Statement on "Virginity Testing"

Nov 7, 2019

View More

Exhibit 1-6

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use MIFEPREX safely and effectively. See full prescribing information for MIFEPREX.

MIFEPREX® (mifepristone) tablets, for oral use
Initial U.S. Approval: 2000

WARNING: SERIOUS AND SOMETIMES FATAL INFECTIONS OR BLEEDING

See full prescribing information for complete boxed warning.

Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following MIFEPREX use.

- **Atypical Presentation of Infection. Patients with serious bacterial infections and sepsis can present without fever, bacteremia or significant findings on pelvic examination. A high index of suspicion is needed to rule out serious infection and sepsis. (5.1)**
- **Bleeding. Prolonged heavy bleeding may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed. (5.2)**

MIFEPREX is only available through a restricted program called the MIFEPREX REMS Program (5.3).
Before prescribing MIFEPREX, inform the patient about these risks.
Ensure the patient knows whom to call and what to do if she experiences sustained fever, severe abdominal pain, prolonged heavy bleeding, or syncope, or if she experiences abdominal pain or discomfort or general malaise for more than 24 hours after taking misoprostol.
Advise the patient to take the MEDICATION GUIDE with her if she visits an emergency room or another healthcare provider who did not prescribe MIFEPREX, so that provider knows that she is undergoing a medical abortion. (5.1, 5.2)

----------RECENT MAJOR CHANGES----------

Boxed Warning	3/2016
Indications and Usage (1)	3/2016
Dosage and Administration, Dosing Regimen (2.1)	3/2016
Dosage and Administration, Post-treatment Assessment: Day 7 to 14 (2.3)	3/2016
Warnings and Precautions, MIFEPREX REMS Program (5.3)	3/2016
Warnings and Precautions, Ectopic Pregnancy (5.4)	3/2016

----------INDICATIONS AND USAGE----------

MIFEPREX is a progestin antagonist indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. (1)

----------DOSAGE AND ADMINISTRATION----------

- 200 mg MIFEPREX on Day 1, followed 24-48 hours after MIFEPREX dosing by 800 mcg buccal misoprostol. (2.1)
- Instruct the patient what to do if significant adverse reactions occur. (2.2)
- Follow-up is needed to confirm complete termination of pregnancy. (2.3)

----------DOSAGE FORMS AND STRENGTHS----------

Tablets containing 200 mg of mifepristone each, supplied as 1 tablet on one blister card (3)

----------CONTRAINDICATIONS----------

- Confirmed/suspected ectopic pregnancy or undiagnosed adnexal mass (4)
- Chronic adrenal failure (4)
- Concurrent long-term corticosteroid therapy (4)
- History of allergy to mifepristone, misoprostol, or other prostaglandins (4)
- Hemorrhagic disorders or concurrent anticoagulant therapy (4)
- Inherited porphyria (4)
- Intrauterine device (IUD) in place (4)

----------WARNINGS AND PRECAUTIONS----------

- Ectopic pregnancy: Exclude before treatment. (5.4)
- Rhesus immunization: Prevention needed as for surgical abortion. (5.5)

----------ADVERSE REACTIONS----------

Most common adverse reactions (>15%) are nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Danco Laboratories, LLC at 1-877-432-7596 or medicaldirector@earlyoptionpill.com or www.earlyoptionpill.com or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------DRUG INTERACTIONS----------

- CYP3A4 inducers can lower mifepristone concentrations. (7.1)
- CYP3A4 inhibitors can increase mifepristone concentrations. Use with caution. (7.2)
- CYP3A4 substrate concentrations can be increased. Caution with coadministration of substrates with narrow therapeutic margin. (7.3)

----------USE IN SPECIFIC POPULATIONS----------

- Pregnancy: Risk of fetal malformations in ongoing pregnancy if not terminated is unknown. (8.1)

See 17 for PATIENT COUNSELING INFORMATION, Medication Guide.

Revised: 3/2016

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: SERIOUS AND SOMETIMES FATAL INFECTIONS OR BLEEDING

Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following MIFEPREX use. No causal relationship between the use of MIFEPREX and misoprostol and these events has been established.

- **Atypical Presentation of Infection. Patients with serious bacterial infections (e.g., *Clostridium sordellii*) and sepsis can present without fever, bacteremia, or significant findings on pelvic examination following an abortion. Very rarely, deaths have been reported in patients who presented without fever, with or without abdominal pain, but with leukocytosis with a marked left shift, tachycardia, hemoconcentration, and general malaise. A high index of suspicion is needed to rule out serious infection and sepsis *[see Warnings and Precautions (5.1)]*.**
- **Bleeding. Prolonged heavy bleeding may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed. Advise patients to seek immediate medical attention if they experience prolonged heavy vaginal bleeding *[see Warnings and Precautions (5.2)]*.**

Because of the risks of serious complications described above, MIFEPREX is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the MIFEPREX REMS Program *[see Warnings and Precautions (5.3)]*.

Before prescribing MIFEPREX, inform the patient about the risk of these serious events. Ensure that the patient knows whom to call and what to do, including going to an Emergency Room if none of the provided contacts are reachable, if she experiences sustained fever, severe abdominal pain, prolonged heavy bleeding, or syncope, or if she experiences abdominal pain or discomfort, or general malaise (including weakness, nausea, vomiting or diarrhea) for more than 24 hours after taking misoprostol.

Advise the patient to take the Medication Guide with her if she visits an emergency room or a healthcare provider who did not prescribe MIFEPREX, so that the provider knows that she is undergoing a medical abortion.

1 INDICATIONS AND USAGE

MIFEPREX is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation.

2 DOSAGE AND ADMINISTRATION

2.1 Dosing Regimen

For purposes of this treatment, pregnancy is dated from the first day of the last menstrual period. The duration of pregnancy may be determined from menstrual history and clinical examination. Assess the pregnancy by ultrasonographic scan if the duration of pregnancy is uncertain or if ectopic pregnancy is suspected.

Remove any intrauterine device ("IUD") before treatment with MIFEPREX begins [*see Contraindications (4)*].

The dosing regimen for MIFEPREX and misoprostol is:

- MIFEPREX 200 mg orally + misoprostol 800 mcg buccally
  - *Day One:* MIFEPREX Administration
    One 200 mg tablet of MIFEPREX is taken in a single oral dose.
  - *Day Two or Three:* Misoprostol Administration (minimum 24-hour interval between MIFEPREX and misoprostol)
    Four 200 mcg tablets (total dose 800 mcg) of misoprostol are taken by the buccal route.

    Tell the patient to place two 200 mcg misoprostol tablets in each cheek pouch (the area between the cheek and gums) for 30 minutes and then swallow any remnants with water or another liquid (see Figure 1).

    Figure 1

2 pills between cheek and gum on left side + 2 pills between cheek and gum on right side

Patients taking MIFEPREX must take misoprostol within 24 to 48 hours after taking MIFEPREX. The effectiveness of the regimen may be lower if misoprostol is administered less than 24 hours or more than 48 hours after mifepristone administration.

Because most women will expel the pregnancy within 2 to 24 hours of taking misoprostol *[see Clinical Studies (14)]*, discuss with the patient an appropriate location for her to be when she takes the misoprostol, taking into account that expulsion could begin within 2 hours of administration.

2.2 Patient Management Following Misoprostol Administration

During the period immediately following the administration of misoprostol, the patient may need medication for cramps or gastrointestinal symptoms *[see Adverse Reactions (6)].*

Give the patient:

- Instructions on what to do if significant discomfort, excessive vaginal bleeding or other adverse reactions occur
- A phone number to call if she has questions following the administration of the misoprostol

- The name and phone number of the healthcare provider who will be handling emergencies.

2.3 Post-treatment Assessment: Day 7 to 14

Patients should follow-up with their healthcare provider approximately 7 to 14 days after the administration of MIFEPREX. This assessment is very important to confirm that complete termination of pregnancy has occurred and to evaluate the degree of bleeding. Termination can be confirmed by medical history, clinical examination, human Chorionic Gonadotropin (hCG) testing, or ultrasonographic scan. Lack of bleeding following treatment usually indicates failure; however, prolonged or heavy bleeding is not proof of a complete abortion.

The existence of debris in the uterus (e.g., if seen on ultrasonography) following the treatment procedure will not necessarily require surgery for its removal.

Women should expect to experience vaginal bleeding or spotting for an average of 9 to 16 days. Women report experiencing heavy bleeding for a median duration of 2 days. Up to 8% of women may experience some type of bleeding for more than 30 days. Persistence of heavy or moderate vaginal bleeding at the time of follow-up, however, could indicate an incomplete abortion.

If complete expulsion has not occurred, but the pregnancy is not ongoing, women may be treated with another dose of misoprostol 800 mcg buccally. There have been rare reports of uterine rupture in women who took Mifeprex and misoprostol, including women with prior uterine rupture or uterine scar and women who received multiple doses of misoprostol within 24 hours. Women who choose to use a repeat dose of misoprostol should have a follow-up visit with their healthcare provider in approximately 7 days to assess for complete termination.

Surgical evacuation is recommended to manage ongoing pregnancies after medical abortion *[see Use in Specific Populations (8.1)]*. Advise the patient whether you will provide such care or will refer her to another provider as part of counseling prior to prescribing MIFEPREX.

2.4 Contact for Consultation

For consultation 24 hours a day, 7 days a week with an expert in mifepristone, call Danco Laboratories at 1-877-4 Early Option (1-877-432-7596).

3 DOSAGE FORMS AND STRENGTHS

Tablets containing 200 mg of mifepristone each, supplied as 1 tablet on one blister card. MIFEPREX tablets are light yellow, cylindrical, and bi-convex tablets, approximately 11 mm in diameter and imprinted on one side with “MF.”

4 CONTRAINDICATIONS

- Administration of MIFEPREX and misoprostol for the termination of pregnancy (the “treatment procedure”) is contraindicated in patients with any of the following conditions:
  - Confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass (the treatment procedure will not be effective to terminate an ectopic pregnancy) *[see Warnings and Precautions (5.4)]*
  - Chronic adrenal failure (risk of acute renal insufficiency)
  - Concurrent long-term corticosteroid therapy (risk of acute renal insufficiency)

- History of allergy to mifepristone, misoprostol, or other prostaglandins (allergic reactions including anaphylaxis, angioedema, rash, hives, and itching have been reported *[see Adverse Reactions (6.2)]*)
- Hemorrhagic disorders or concurrent anticoagulant therapy (risk of heavy bleeding)
- Inherited porphyrias (risk of worsening or of precipitation of attacks)

- Use of MIFEPREX and misoprostol for termination of intrauterine pregnancy is contraindicated in patients with an intrauterine device ("IUD") in place (the IUD might interfere with pregnancy termination). If the IUD is removed, MIFEPREX may be used.

5 WARNINGS AND PRECAUTIONS

5.1 Infection and Sepsis

As with other types of abortion, cases of serious bacterial infection, including very rare cases of fatal septic shock, have been reported following the use of MIFEPREX *[see Boxed Warning]*. Healthcare providers evaluating a patient who is undergoing a medical abortion should be alert to the possibility of this rare event. A sustained (> 4 hours) fever of 100.4°F or higher, severe abdominal pain, or pelvic tenderness in the days after a medical abortion may be an indication of infection.

A high index of suspicion is needed to rule out sepsis (e.g., from *Clostridium sordellii*) if a patient reports abdominal pain or discomfort or general malaise (including weakness, nausea, vomiting or diarrhea) more than 24 hours after taking misoprostol. Very rarely, deaths have been reported in patients who presented without fever, with or without abdominal pain, but with leukocytosis with a marked left shift, tachycardia, hemoconcentration, and general malaise. No causal relationship between MIFEPREX and misoprostol use and an increased risk of infection or death has been established. *Clostridium sordellii* infections have also been reported very rarely following childbirth (vaginal delivery and caesarian section), and in other gynecologic and non-gynecologic conditions.

5.2 Uterine Bleeding

Uterine bleeding occurs in almost all patients during a medical abortion. Prolonged heavy bleeding (soaking through two thick full-size sanitary pads per hour for two consecutive hours) may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed to prevent the development of hypovolemic shock. Counsel patients to seek immediate medical attention if they experience prolonged heavy vaginal bleeding following a medical abortion *[see Boxed Warning]*.

Women should expect to experience vaginal bleeding or spotting for an average of 9 to 16 days. Women report experiencing heavy bleeding for a median duration of 2 days. Up to 8% of all subjects may experience some type of bleeding for 30 days or more. In general, the duration of bleeding and spotting increased as the duration of the pregnancy increased.

Decreases in hemoglobin concentration, hematocrit, and red blood cell count may occur in women who bleed heavily.

Excessive uterine bleeding usually requires treatment by uterotonics, vasoconstrictor drugs, surgical uterine evacuation, administration of saline infusions, and/or blood transfusions. Based on data from several large clinical trials, vasoconstrictor drugs were used in 4.3% of all subjects, there was a decrease in hemoglobin of more than 2 g/dL in 5.5% of subjects, and blood transfusions were administered to ≤ 0.1% of subjects. Because heavy bleeding requiring

surgical uterine evacuation occurs in about 1% of patients, special care should be given to patients with hemostatic disorders, hypocoagulability, or severe anemia.

5.3 MIFEPREX REMS Program

MIFEPREX is available only through a restricted program under a REMS called the MIFEPREX REMS Program, because of the risks of serious complications *[see Warnings and Precautions (5.1, 5.2)]*.

Notable requirements of the MIFEPREX REMS Program include the following:

- Prescribers must be certified with the program by completing the Prescriber Agreement Form
- Patients must sign a Patient Agreement Form.
- MIFEPREX must be dispensed to patients only in certain healthcare settings, specifically clinics, medical offices and hospitals by or under the supervision of a certified prescriber

Further information is available at 1-877-4 Early Option (1-877-432-7596).

5.4 Ectopic Pregnancy

MIFEPREX is contraindicated in patients with a confirmed or suspected ectopic pregnancy because MIFEPREX is not effective for terminating ectopic pregnancies *[see Contraindications (4)].* Healthcare providers should remain alert to the possibility that a patient who is undergoing a medical abortion could have an undiagnosed ectopic pregnancy because some of the expected symptoms experienced with a medical abortion (abdominal pain, uterine bleeding) may be similar to those of a ruptured ectopic pregnancy. The presence of an ectopic pregnancy may have been missed even if the patient underwent ultrasonography prior to being prescribed MIFEPREX.

Women who became pregnant with an IUD in place should be assessed for ectopic pregnancy.

5.5 Rhesus Immunization

The use of MIFEPREX is assumed to require the same preventive measures as those taken prior to and during surgical abortion to prevent rhesus immunization.

6 ADVERSE REACTIONS

The following adverse reactions are described in greater detail in other sections:

- Infection and sepsis *[see Warnings and Precautions (5.1)]*
- Uterine bleeding *[see Warnings and Precautions (5.2)]*

6.1 Clinical Trials Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

Information presented on common adverse reactions relies solely on data from US studies, because rates reported in non-US studies were markedly lower and are not likely generalizable to the US population. In three US clinical studies totaling 1,248 women through 70 days gestation who used mifepristone 200 mg orally followed 24-48 hours later by misoprostol 800 mcg buccally, women reported adverse reactions in diaries and in interviews at the follow-up visit. These studies enrolled generally healthy women of reproductive age without contraindications to mifepristone or misoprostol use according to the MIFEPREX product label.

Gestational age was assessed prior to study enrollment using the date of the woman's last menstrual period, clinical evaluation, and/or ultrasound examination.

About 85% of patients report at least one adverse reaction following administration of MIFEPREX and misoprostol, and many can be expected to report more than one such reaction. The most commonly reported adverse reactions (>15%) were nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness (see Table 1). The frequency of adverse reactions varies between studies and may be dependent on many factors including the patient population and gestational age.

Abdominal pain/cramping is expected in all medical abortion patients and its incidence is not reported in clinical studies. Treatment with MIFEPREX and misoprostol is designed to induce uterine bleeding and cramping to cause termination of an intrauterine pregnancy. Uterine bleeding and cramping are expected consequences of the action of MIFEPREX and misoprostol as used in the treatment procedure. Most women can expect bleeding more heavily than they do during a heavy menstrual period *[see Warnings and Precautions (5.2)]*.

Table 1 lists the adverse reactions reported in U.S. clinical studies with incidence >15% of women.

Table 1
Adverse Reactions Reported in Women Following Administration of Mifepristone (oral) and Misoprostol (buccal) in U.S. Clinical Studies

Adverse Reaction	# US studies	Number of Evaluable Women	Range of frequency (%)	Upper Gestational Age of Studies Reporting Outcome
Nausea	3	1,248	51-75%	70 days
Weakness	2	630	55-58%	63 days
Fever/chills	1	414	48%	63 days
Vomiting	3	1,248	37-48%	70 days
Headache	2	630	41-44%	63 days
Diarrhea	3	1,248	18-43%	70 days
Dizziness	2	630	39-41%	63 days

One study provided gestational-age stratified adverse reaction rates for women who were 57-63 and 64-70 days; there was little difference in frequency of the reported common adverse reactions by gestational age.

Information on serious adverse reactions was reported in six U.S. and four non-U.S. clinical studies, totaling 30,966 women through 70 days gestation who used mifepristone 200 mg orally followed 24-48 hours later by misoprostol 800 mcg buccally. Serious adverse reaction rates were similar between U.S. and non-U.S. studies, so rates from both U.S. and non-U.S. studies are presented. In the U.S. studies, one studied women through 56 days gestation, four through 63 days gestation, and one through 70 days gestation, while in the non-U.S. studies, two studied women through 63 days gestation, and two through 70 days gestation. Serious adverse reactions were reported in <0.5% of women. Information from the U.S. and non-U.S. studies is presented in Table 2.

Table 2
Serious Adverse Reactions Reported in Women Following Administration of Mifepristone (oral) and Misoprostol (buccal) in U.S. and Non-US Clinical Studies

Adverse Reaction	US			Non-US		
	# of studies	Number of Evaluable Women	Range of frequency (%)	# of studies	Number of Evaluable Women	Range of frequency (%)
Transfusion	4	17,774	0.03-0.5%	3	12,134	0-0.1%
Sepsis	1	629	0.2%	1	11,155	<0.01%*
ER visit	2	1,043	2.9-4.6%	1	95	0
Hospitalization Related to Medical Abortion	3	14,339	0.04-0.6%	3	1,286	0-0.7%
Infection without sepsis	1	216	0	1	11,155	0.2%
Hemorrhage	NR	NR	NR	1	11,155	0.1%

NR= Not reported
* This outcome represents a single patient who experienced death related to sepsis.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of MIFEPREX and misoprostol. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Infections and infestations: post-abortal infection (including endometritis, endomyometritis, parametritis, pelvic infection, pelvic inflammatory disease, salpingitis)
Blood and the lymphatic system disorders: anemia
Immune system disorders: allergic reaction (including anaphylaxis, angioedema, hives, rash, itching)
Psychiatric disorders: anxiety
Cardiac disorders: tachycardia (including racing pulse, heart palpitations, heart pounding)
Vascular disorders: syncope, fainting, loss of consciousness, hypotension (including orthostatic), light-headedness
Respiratory, thoracic and mediastinal disorders: shortness of breath
Gastrointestinal disorders: dyspepsia
Musculoskeletal, connective tissue and bone disorders: back pain, leg pain
Reproductive system and breast disorders: uterine rupture, ruptured ectopic pregnancy, hematometra, leukorrhea
General disorders and administration site conditions: pain

7 DRUG INTERACTIONS

7.1 Drugs that May Reduce MIFEPREX Exposure (Effect of CYP 3A4 Inducers on MIFEPREX)

CYP450 3A4 is primarily responsible for the metabolism of mifepristone. CYP3A4 inducers such as rifampin, dexamethasone, St. John's Wort, and certain anticonvulsants (such as phenytoin, phenobarbital, carbamazepine) may induce mifepristone metabolism (lowering serum concentrations of mifepristone). Whether this action has an impact on the efficacy of the dose

regimen is unknown. Refer to the follow-up assessment *[see Dosage and Administration (2.3)]* to verify that treatment has been successful.

7.2 Drugs that May Increase MIFEPREX Exposure (Effect of CYP 3A4 Inhibitors on MIFEPREX)

Although specific drug or food interactions with mifepristone have not been studied, on the basis of this drug's metabolism by CYP 3A4, it is possible that ketoconazole, itraconazole, erythromycin, and grapefruit juice may inhibit its metabolism (increasing serum concentrations of mifepristone). MIFEPREX should be used with caution in patients currently or recently treated with CYP 3A4 inhibitors.

7.3 Effects of MIFEPREX on Other Drugs (Effect of MIFEPREX on CYP 3A4 Substrates)

Based on *in vitro* inhibition information, coadministration of mifepristone may lead to an increase in serum concentrations of drugs that are CYP 3A4 substrates. Due to the slow elimination of mifepristone from the body, such interaction may be observed for a prolonged period after its administration. Therefore, caution should be exercised when mifepristone is administered with drugs that are CYP 3A4 substrates and have narrow therapeutic range.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Mifepristone is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. Risks to pregnant women are discussed throughout the labeling.

Refer to misoprostol labeling for risks to pregnant women with the use of misoprostol.

The risk of adverse developmental outcomes with a continued pregnancy after a failed pregnancy termination with MIFEPREX in a regimen with misoprostol is unknown; however, the process of a failed pregnancy termination could disrupt normal embryo-fetal development and result in adverse developmental effects. Birth defects have been reported with a continued pregnancy after a failed pregnancy termination with MIFEPREX in a regimen with misoprostol. In animal reproduction studies, increased fetal losses were observed in mice, rats, and rabbits and skull deformities were observed in rabbits with administration of mifepristone at doses lower than the human exposure level based on body surface area.

Data

Animal Data

In teratology studies in mice, rats and rabbits at doses of 0.25 to 4.0 mg/kg (less than 1/100 to approximately 1/3 the human exposure based on body surface area), because of the antiprogestational activity of mifepristone,fetal losses were much higher than in control animals. Skull deformaties were detected in rabbit studies at approximately 1/6 the human exposure, although no teratogenic effects of mifepristone have been observed to date in rats or mice. These deformities were most likely due to the mechanical effects of uterine contractions resulting from inhibition of progesterone action.

8.2 Lactation

MIFEPREX is present in human milk. Limited data demonstrate undetectable to low levels of the drug in human milk with the relative (weight-adjusted) infant dose 0.5% or less as compared to maternal dosing. There is no information on the effects of MIFEPREX in a regimen with

misoprostol in a breastfed infant or on milk production. Refer to misoprostol labeling for lactation information with the use of misoprostol. The developmental and health benefits of breast-feeding should be considered along with any potential adverse effects on the breast-fed child from MIFEPREX in a regimen with misoprostol.

8.4 Pediatric Use

Safety and efficacy of MIFEPREX have been established in pregnant females. Data from a clinical study of MIFEPREX that included a subset of 322 females under age 17 demonstrated a safety and efficacy profile similar to that observed in adults.

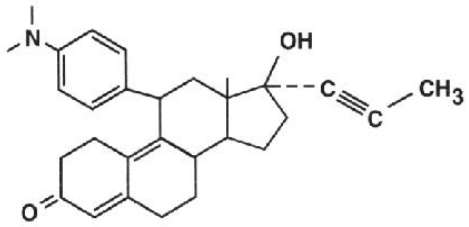
10 OVERDOSAGE

No serious adverse reactions were reported in tolerance studies in healthy non-pregnant female and healthy male subjects where mifepristone was administered in single doses greater than 1800 mg (ninefold the recommended dose for medical abortion). If a patient ingests a massive overdose, she should be observed closely for signs of adrenal failure.

11 DESCRIPTION

MIFEPREX tablets each contain 200 mg of mifepristone, a synthetic steroid with antiprogestational effects. The tablets are light yellow in color, cylindrical, and bi-convex, and are intended for oral administration only. The tablets include the inactive ingredients colloidal silica anhydrous, corn starch, povidone, microcrystalline cellulose, and magnesium stearate.

Mifepristone is a substituted 19-nor steroid compound chemically designated as 11ß-[*p*-(Dimethylamino)phenyl]-17ß-hydroxy-17-(1-propynyl)estra-4,9-dien-3-one. Its empirical formula is $C_{29}H_{35}NO_2$. Its structural formula is:



The compound is a yellow powder with a molecular weight of 429.6 and a melting point of 192-196°C. It is very soluble in methanol, chloroform and acetone and poorly soluble in water, hexane and isopropyl ether.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The anti-progestational activity of mifepristone results from competitive interaction with progesterone at progesterone-receptor sites. Based on studies with various oral doses in several animal species (mouse, rat, rabbit, and monkey), the compound inhibits the activity of endogenous or exogenous progesterone, resulting in effects on the uterus and cervix that, when combined with misoprostol, result in termination of an intrauterine pregnancy.

During pregnancy, the compound sensitizes the myometrium to the contraction-inducing activity of prostaglandins.

12.2 Pharmacodynamics

Use of MIFEPREX in a regimen with misoprostol disrupts pregnancy by causing decidual necrosis, myometrial contractions, and cervical softening, leading to the expulsion of the products of conception.

Doses of 1 mg/kg or greater of mifepristone have been shown to antagonize the endometrial and myometrial effects of progesterone in women.

Antiglucocorticoid and antiandrogenic activity: Mifepristone also exhibits antiglucocorticoid and weak antiandrogenic activity. The activity of the glucocorticoid dexamethasone in rats was inhibited following doses of 10 to 25 mg/kg of mifepristone. Doses of 4.5 mg/kg or greater in human beings resulted in a compensatory elevation of adrenocorticotropic hormone (ACTH) and cortisol. Antiandrogenic activity was observed in rats following repeated administration of doses from 10 to 100 mg/kg.

12.3 Pharmacokinetics

Mifepristone is rapidly absorbed after oral ingestion with non-linear pharmacokinetics for Cmax after single oral doses of 200 mg and 600 mg in healthy subjects.

Absorption

The absolute bioavailability of a 20 mg mifepristone oral dose in women of childbearing age is 69%. Following oral administration of a single dose of 600 mg, mifepristone is rapidly absorbed, with a peak plasma concentration of 1.98 ± 1.0 mg/L occurring approximately 90 minutes after ingestion.

Following oral administration of a single dose of 200 mg in healthy men (n=8), mean Cmax was 1.77 ± 0.7 mg/L occurring approximately 45 minutes after ingestion. Mean $AUC_{0-\infty}$ was 25.8 ± 6.2 mg*hr/L.

Distribution

Mifepristone is 98% bound to plasma proteins, albumin, and α_1-acid glycoprotein. Binding to the latter protein is saturable, and the drug displays nonlinear kinetics with respect to plasma concentration and clearance.

Elimination

Following a distribution phase, elimination of mifepristone is slow at first (50% eliminated between 12 and 72 hours) and then becomes more rapid with a terminal elimination half-life of 18 hours.

Metabolism

Metabolism of mifepristone is primarily via pathways involving N-demethylation and terminal hydroxylation of the 17-propynyl chain. *In vitro* studies have shown that CYP450 3A4 is primarily responsible for the metabolism. The three major metabolites identified in humans are: (1) RU 42 633, the most widely found in plasma, is the N-monodemethylated metabolite; (2) RU 42 848, which results from the loss of two methyl groups from the 4-dimethylaminophenyl in position 11ß; and (3) RU 42 698, which results from terminal hydroxylation of the 17-propynyl chain.

Excretion

By 11 days after a 600 mg dose of tritiated compound, 83% of the drug has been accounted for by the feces and 9% by the urine. Serum concentrations are undetectable by 11 days.

Specific Populations

The effects of age, hepatic disease and renal disease on the safety, efficacy and pharmacokinetics of mifepristone have not been investigated.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

No long-term studies to evaluate the carcinogenic potential of mifepristone have been performed.

Mutagenesis

Results from studies conducted *in vitro* and in animals have revealed no genotoxic potential for mifepristone. Among the tests carried out were: Ames test with and without metabolic activation; gene conversion test in *Saccharomyces cerevisiae* D4 cells; forward mutation in *Schizosaccharomyces pompe* P1 cells; induction of unscheduled DNA synthesis in cultured HeLa cells; induction of chromosome aberrations in CHO cells; *in vitro* test for gene mutation in V79 Chinese hamster lung cells; and micronucleus test in mice.

Impairment of Fertility

In rats, administration of 0.3 mg/kg mifepristone per day caused severe disruption of the estrus cycles for the three weeks of the treatment period. Following resumption of the estrus cycle, animals were mated and no effects on reproductive performance were observed.

14 CLINICAL STUDIES

Safety and efficacy data from clinical studies of mifepristone 200 mg orally followed 24-48 hours later by misoprostol 800 mcg buccally through 70 days gestation are reported below. Success was defined as the complete expulsion of the products of conception without the need for surgical intervention. The overall rates of success and failure, shown by reason for failure based on 22 worldwide clinical studies (including 7 U.S. studies) appear in Table 3.

The demographics of women who participated in the U.S. clinical studies varied depending on study location and represent the racial and ethnic variety of American females. Females of all reproductive ages were represented, including females less than 18 and more than 40 years of age; most were 27 years or younger.

Table 3
Outcome Following Treatment with Mifepristone (oral) and Misoprostol (buccal) Through 70 Days Gestation

	U.S. Trials	Non-U.S. Trials
N	16,794	18,425
Complete Medical Abortion	97.4%	96.2%
Surgical Intervention*	2.6%	3.8%
Ongoing Pregnancy**	0.7%	0.9%

* Reasons for surgical intervention include ongoing pregnancy, medical necessity, persistent or heavy bleeding after treatment, patient request, or incomplete expulsion.
** Ongoing pregnancy is a subcategory of surgical intervention, indicating the percent of women who have surgical intervention due to an ongoing pregnancy.

The results for clinical studies that reported outcomes, including failure rates for ongoing pregnancy, by gestational age are presented in Table 4.

Table 4
Outcome by Gestational Age Following Treatment with Mifepristone and Misoprostol (buccal) for U.S. and Non-U.S. Clinical Studies

	<49 days			50-56 days			57-63 days			64-70 days		
	N	%	Number of Evaluable Studies	N	%	Number of Evaluable Studies	N	%	Number of Evaluable Studies	N	%	Number of Evaluable Studies
Complete medical abortion	12,046	98.1	10	3,941	96.8	7	2,294	94.7	9	479	92.7	4
Surgical intervention for ongoing pregnancy	10,272	0.3	6	3,788	0.8	6	2,211	2	8	453	3.1	3

One clinical study asked subjects through 70 days gestation to estimate when they expelled the pregnancy, with 70% providing data. Of these, 23-38% reported expulsion within 3 hours and over 90% within 24 hours of using misoprostol.

16 HOW SUPPLIED/STORAGE AND HANDLING

MIFEPREX is only available through a restricted program called the MIFEPREX REMS Program *[see Warnings and Precautions (5.3)].*

MIFEPREX is supplied as light yellow, cylindrical, and bi-convex tablets imprinted on one side with “MF.” Each tablet contains 200 mg of mifepristone. One tablet is individually blistered on one blister card that is packaged in an individual package (National Drug Code 64875-001-01).

Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP Controlled Room Temperature].

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide), included with each package of MIFEPREX. Additional copies of the Medication Guide are available by contacting Danco Laboratories at 1-877-4 Early Option (1-877-432-7596) or from www.earlyoptionpill.com.

Serious Infections and Bleeding

- Inform the patient that uterine bleeding and uterine cramping will occur [see Warnings and Precautions (5.2)].
- Advise the patient that serious and sometimes fatal infections and bleeding can occur very rarely [see Warnings and Precautions (5.1, 5.2)].
- MIFEPREX is only available through a restricted program called the MIFEPREX REMS Program [see Warnings and Precautions (5.3)]. Under the Mifeprex REMS Program:
    - Patients must sign a Patient Agreement Form.
    - MIFEPREX is only available in clinics, medical offices and hospitals and not through retail pharmacies.

Provider Contacts and Actions in Case of Complications

- Ensure that the patient knows whom to call and what to do, including going to an Emergency Room if none of the provided contacts are reachable, or if she experiences complications including prolonged heavy bleeding, severe abdominal pain, or sustained fever *[see Boxed Warning]*.
- Advise the patient to take the Medication Guide with her if she visits an emergency room or another healthcare provider who did not prescribe MIFEPREX, so that provider will be aware that the patient is undergoing a medical abortion with MIFEPREX.

Compliance with Treatment Schedule and Follow-up Assessment

- Advise the patient that it is necessary to complete the treatment schedule, including a follow-up assessment approximately 7 to14 days after taking MIFEPREX *[see Dosage and Administration (2.3)]*.
- Explain that
    - prolonged heavy vaginal bleeding is not proof of a complete abortion,
    - if the treatment fails and the pregnancy continues, the risk of fetal malformation is unknown,
    - it is recommended that ongoing pregnancy be managed by surgical termination *[see Dosage and Administration (2.3)]*. Advise the patient whether you will provide such care or will refer her to another provider.

Subsequent Fertility

- Inform the patient that another pregnancy can occur following medical abortion and before resumption of normal menses.
- Inform the patient that contraception can be initiated as soon as pregnancy expulsion has been confirmed, or before she resumes sexual intercourse.

MIFEPREX is a registered trademark of Danco Laboratories, LLC.

Manufactured for:
Danco Laboratories, LLC
P.O. Box 4816
New York, NY 10185
1-877-4 Early Option (1-877-432-7596)
www.earlyoptionpill.com

3/2016

MEDICATION GUIDE

Mifeprex (MIF-eh-prex) (mifepristone) tablets, for oral use

Read this information carefully before taking Mifeprex and misoprostol. It will help you understand how the treatment works. This Medication Guide does not take the place of talking with your healthcare provider.

What is the most important information I should know about Mifeprex?

What symptoms should I be concerned with? Although cramping and bleeding are an expected part of ending a pregnancy, rarely, serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion, or childbirth. Seeking medical attention as soon as possible is needed in these circumstances. Serious infection has resulted in death in a very small number of cases. There is no information that use of Mifeprex and misoprostol caused these deaths. If you have any questions, concerns, or problems, or if you are worried about any side effects or symptoms, you should contact your healthcare provider. You can write down your healthcare provider's telephone number here _____.

Be sure to contact your healthcare provider promptly if you have any of the following:

- **Heavy Bleeding.** Contact your healthcare provider right away if you bleed enough to soak through two thick full-size sanitary pads per hour for two consecutive hours or if you are concerned about heavy bleeding. In about 1 out of 100 women, bleeding can be so heavy that it requires a surgical procedure (surgical aspiration or D&C).
- **Abdominal Pain or "Feeling Sick."** If you have abdominal pain or discomfort, or you are "feeling sick," including weakness, nausea, vomiting, or diarrhea, with or without fever, more than 24 hours after taking misoprostol, you should contact your healthcare provider without delay. These symptoms may be a sign of a serious infection or another problem (including an ectopic pregnancy, a pregnancy outside the womb).
- **Fever.** In the days after treatment, if you have a fever of 100.4°F or higher that lasts for more than 4 hours, you should contact your healthcare provider right away. Fever may be a symptom of a serious infection or another problem.

If you cannot reach your healthcare provider, go to the nearest hospital emergency room. Take this Medication Guide with you. When you visit an emergency room or a healthcare provider who did not give you your Mifeprex, you should give them your Medication Guide so that they understand that you are having a medical abortion with Mifeprex.

What to do if you are still pregnant after Mifeprex with misoprostol treatment. If you are still pregnant, your healthcare provider will talk with you about a surgical procedure to end your pregnancy. In many cases, this surgical procedure can be done in the office/clinic. The chance of birth defects if the pregnancy is not ended is unknown.

Talk with your healthcare provider. Before you take Mifeprex, you should read this Medication Guide and you and your healthcare provider should discuss the benefits and risks of your using Mifeprex.

What is Mifeprex?

Mifeprex is used in a regimen with another prescription medicine called misoprostol, to end an early pregnancy. Early pregnancy means it is 70 days (10 weeks) or less since your last menstrual period began. Mifeprex is not approved for ending pregnancies that are further along. Mifeprex blocks a hormone needed for your pregnancy to continue. When you use Mifeprex on Day 1, you also need to take another medicine called misoprostol 24 to 48 hours after you take Mifeprex, to cause the pregnancy to be passed from your uterus.

The pregnancy is likely to be passed from your uterus within 2 to 24 hours after taking Mifeprex and misoprostol. When the pregnancy is passed from the uterus, you will have bleeding and cramping that will likely be heavier than your usual period. About 2 to 7 out of 100 women taking Mifeprex will need a surgical procedure because the pregnancy did not completely pass from the uterus or to stop bleeding.

Who should not take Mifeprex?

Some women should not take Mifeprex. Do not take Mifeprex if you:

- Have a pregnancy that is more than 70 days (10 weeks). Your healthcare provider may do a clinical examination, an ultrasound examination, or other testing to determine how far along you are in pregnancy.
- Are using an IUD (intrauterine device or system). It must be taken out before you take Mifeprex.
- Have been told by your healthcare provider that you have a pregnancy outside the uterus (ectopic pregnancy).
- Have problems with your adrenal glands (chronic adrenal failure).
- Take a medicine to thin your blood.
- Have a bleeding problem.
- Have porphyria.
- Take certain steroid medicines.
- Are allergic to mifepristone, misoprostol, or medicines that contain misoprostol, such as Cytotec or Arthrotec.

Ask your healthcare provider if you are not sure about all your medical conditions before taking this medicine to find out if you can take Mifeprex.

What should I tell my healthcare provider before taking Mifeprex?

Before you take Mifeprex, tell your healthcare provider if you:

- cannot follow-up within approximately 7 to 14 days of your first visit
- are breastfeeding. Mifeprex can pass into your breast milk. The effect of the Mifeprex and misoprostol regimen on the breastfed infant or on milk production is unknown.
- are taking medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
  Mifeprex and certain other medicines may affect each other if they are used together. This can cause side effects.

How should I take Mifeprex?

- Mifeprex will be given to you by a healthcare provider in a clinic, medical office, or hospital.
- You and your healthcare provider will plan the most appropriate location for you to take the misoprostol, because it may cause bleeding, cramps, nausea, diarrhea, and other symptoms that usually begin within 2 to 24 hours after taking it.
- Most women will pass the pregnancy within 2 to 24 hours after taking the misoprostol tablets.

Follow the instruction below on how to take Mifeprex and misoprostol:

Mifeprex (1 tablet) orally + misoprostol (4 tablets) buccally

Day 1:

- Take 1 Mifeprex tablet by mouth.
- Your healthcare provider will either give you or prescribe for you 4 misoprostol tablets to take 24 to 48 hours later.

24 to 48 hours after taking Mifeprex:

- Place 2 misoprostol tablets in each cheek pouch (the area between your teeth and cheek - see Figure A) for 30 minutes and then swallow anything left over with a drink of water or another liquid.
- The medicines may not work as well if you take misoprostol sooner than 24 hours after Mifeprex or later than 48 hours after Mifeprex.
- Misoprostol often causes cramps, nausea, diarrhea, and other symptoms. Your healthcare provider may send you home with medicines for these symptoms.

Figure A (2 tablets between your left cheek and gum and 2 tablets between your right cheek and gum).

Follow-up Assessment at Day 7 to 14:

- This follow-up assessment is very important. You must follow-up with your healthcare provider about 7 to 14 days after you have taken Mifeprex to be sure you are well and that you have had bleeding and the pregnancy has passed from your uterus.
- Your healthcare provider will assess whether your pregnancy has passed from your uterus. If your pregnancy continues, the chance that there may be birth defects is unknown. If you are still pregnant, your healthcare provider will talk with you about a surgical procedure to end your pregnancy.
- If your pregnancy has ended, but has not yet completely passed from your uterus, your provider will talk with you about other choices you have, including waiting, taking another dose of misoprostol, or having a surgical procedure to empty your uterus.

When should I begin birth control?

You can become pregnant again right after your pregnancy ends. If you do not want to become pregnant again, start using birth control as soon as your pregnancy ends or before you start having sexual intercourse again.

What should I avoid while taking Mifeprex and misoprostol?

Do not take any other prescription or over-the-counter medicines (including herbal medicines or supplements) at any time during the treatment period without first asking your healthcare provider about them because they may interfere with the treatment. Ask your healthcare provider about what medicines you can take for pain and other side effects.

What are the possible side effects of Mifeprex and misoprostol?

Mifeprex may cause serious side effects. See "What is the most important information I should know about Mifeprex?"

Cramping and bleeding. Cramping and vaginal bleeding are expected with this treatment. Usually, these symptoms mean that the treatment is working. But sometimes you can get cramping and bleeding and still be pregnant. This is why you must follow-up with your healthcare provider approximately 7 to 14 days after taking Mifeprex. See "How should I take Mifeprex?" for more information on your follow-up assessment. If you are not already bleeding after taking Mifeprex, you probably will begin to bleed once you take misoprostol, the medicine you take 24 to 48 hours after Mifeprex. Bleeding or spotting can be expected for an average of 9 to16 days and may last for up to 30 days. Your bleeding may be similar to, or greater than, a normal heavy period. You may see blood clots and tissue. This is an expected part of passing the pregnancy.

The most common side effects of Mifeprex treatment include: nausea, weakness, fever/chills, vomiting, headache, diarrhea and dizziness. Your provider will tell you how to manage any pain or other side effects.These are not all the possible side effects of Mifeprex.

Call your healthcare provider for medical advice about any side effects that bother you or do not go away. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of Mifeprex.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. This Medication Guide summarizes the most important information about Mifeprex. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider for information about Mifeprex that is written for healthcare professionals.

For more information about Mifeprex, go to www.earlyoptionpill.com or call 1-877-4 Early Option (1-877-432-7596).

Manufactured for: *Danco Laboratories, LLC*
P.O. Box 4816
New York, NY 10185
1-877-4 Early Option (1-877-432-7596) www.earlyoptionpill.com

This Medication Guide has been approved by the U.S. Food and Drug Administration. Approval 3/2016

Exhibit 1-7

Original Research

Incidence of Emergency Department Visits and Complications After Abortion

Ushma D. Upadhyay, PhD, MPH, Sheila Desai, MPH, Vera Zlidar, MHS, Tracy A. Weitz, PhD, MPA, Daniel Grossman, MD, Patricia Anderson, MPH, and Diana Taylor, PhD, RNP

OBJECTIVE: To conduct a retrospective observational cohort study to estimate the abortion complication rate, including those diagnosed or treated at emergency departments (EDs).

METHODS: Using 2009–2010 abortion data among women covered by the fee-for-service California Medicaid program and all subsequent health care for 6 weeks after having an abortion, we analyzed reasons for ED visits and estimated the abortion-related complication rate and the adjusted relative risk. Complications were defined as receiving an abortion-related diagnosis or treatment at any source of care within 6 weeks after an abortion. Major complications were defined as requiring hospital admission, surgery, or blood transfusion.

RESULTS: A total of 54,911 abortions among 50,273 fee-for-service Medi-Cal beneficiaries were identified. Among all abortions, 1 of 16 (6.4%, n=3,531) was followed by an ED visit within 6 weeks but only 1 of 115 (0.87%, n=478) resulted in an ED visit for an abortion-related complication. Approximately 1 of 5,491 (0.03%, n=15) involved ambulance transfers to EDs on the day of the abortion. The major complication rate was 0.23% (n=126, 1/436): 0.31% (n=35) for medication abortion, 0.16% (n=57) for first-trimester aspiration abortion, and 0.41% (n=34) for second-trimester or later procedures. The total abortion-related complication rate including all sources of care including EDs and the original abortion facility was 2.1% (n=1,156): 5.2% (n=588) for medication abortion, 1.3% (n=438) for first-trimester aspiration abortion, and 1.5% (n=130) for second-trimester or later procedures.

CONCLUSION: Abortion complication rates are comparable to previously published rates even when ED visits are included and there is no loss to follow-up.

(Obstet Gynecol 2015;0:1–9)

DOI: 10.1097/AOG.0000000000000603

LEVEL OF EVIDENCE: II

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Supported by a University of California, San Francisco National Center of Excellence in Women's Health RAP Grant from Mount Zion Health Fund of the Jewish Community Endowment Fund and an anonymous foundation.

Presented at the North American Forum on Family Planning, October 6–7, 2013, Seattle, Washington.

The authors thank clinical consultants Kristina Ryan, RN, MSN, FNP, and Yvonne Piper, RN, FNP, MS, for their tireless efforts in coding the data; Diana Greene Foster, PhD, for providing expertise in Medi-Cal data analysis; Janley Hsiao, CPC, Billing Manager at San Francisco General Hospital, for providing expertise in Medi-Cal coding; Philip Darney, MD, MSc, for his critical review of the manuscript; and Shayna Lewis, JD, and Roula AbiSamra, MPH, for administration and coordination of the data.

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Financial Disclosure

The authors did not report any potential conflicts of interest.

ISSN: 0029-7844/15

With 1.1 million induced abortions in the United States each year,[1] accurate estimates of abortion complications are paramount to assess and improve quality of care and determine how public policies can most effectively safeguard women's health. Although national abortion-related mortality data exist for the United States,[2] no surveillance system captures abortion-related morbidity. Studies find varying complication rates[3–7] depending on the procedure, weeks of gestation, length of follow-up, and protocols used to detect complications. Furthermore, complication rates are underestimated by low follow-up rates.[5,7–9]

Published complication rates are considered incomplete because they usually do not include those diagnosed at sites other than the original source of care.[10]

Limited research focuses on emergency department (ED) use when examining postabortion care. Because the abortion care delivery system is concentrated in urban centers maldistributed across states,[1] women often travel to obtain abortion care. Thus, women are likely to seek postabortion care at an ED near their home.

Using state Medicaid data, we examine reasons for postabortion visits, contributing to the literature

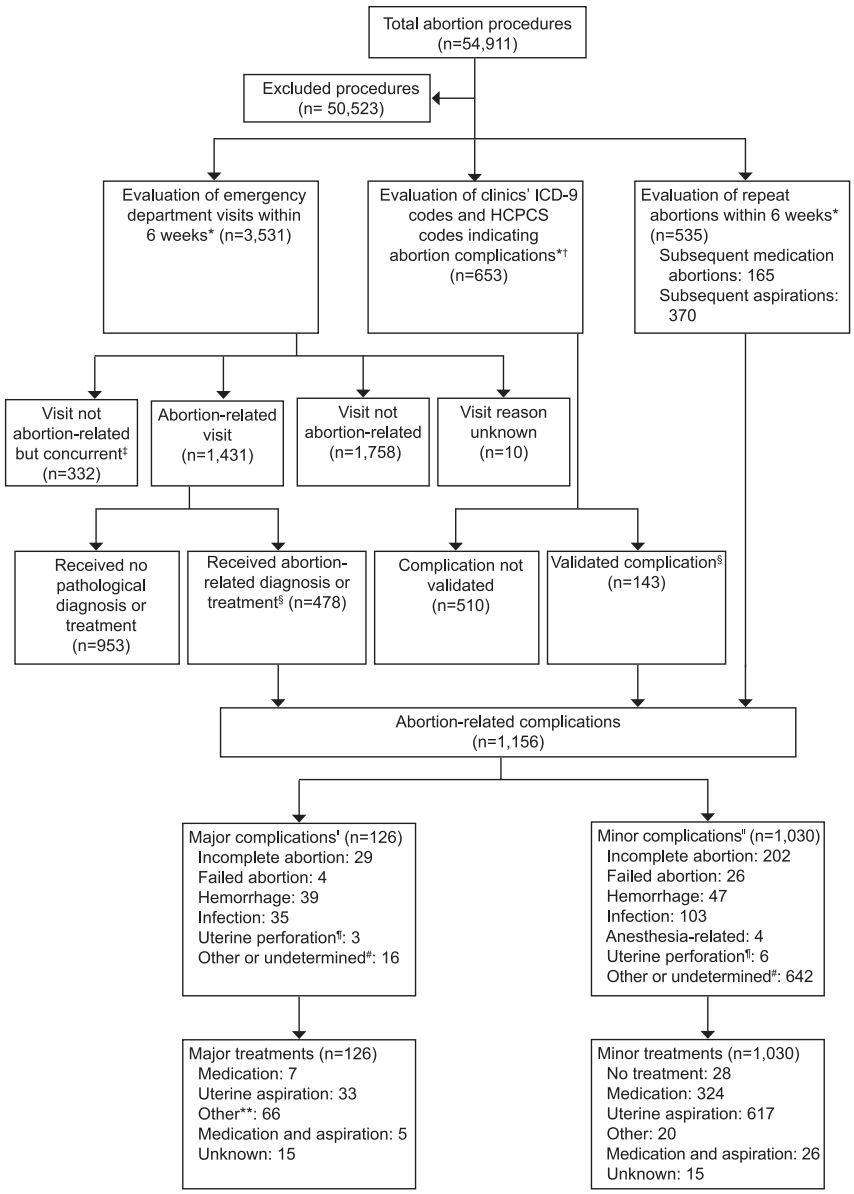

Fig. 1. Process of identification and classification of abortion complications and treatment. ICD-9, International classification of Diseases, 9th Revision; HCPCS, Healthcare Common Procedure Coding System. *Figures presented in the evaluation categories are not mutually exclusive. For example, a complication may have been identified through the evaluation of both emergency department visits and ICD-9 codes and, thus, are represented in both categories. †Includes diagnosis and treatment codes for antibiotics commonly used to treat abortion-related infections, genital tract and pelvic infection, hemorrhage, damage to pelvic organs or tissues, shock, embolism, laparoscopy, laparotomy, and hysterectomy surgeries, and blood transfusions. ‡Includes medical problems that were diagnosed and treated around the time of the abortion procedure such as ectopic pregnancy, molar pregnancy, preexisting medical condition, or concurrent problems present at the time of the procedure. §Confirmed as a complication based on the additional diagnosis or treatment codes, including laboratory tests ordered and medications. ‖Major complications were defined as serious unexpected adverse events requiring hospital admission, surgery, or blood transfusion. Minor complications were all other expected adverse events. ¶Includes one diagnosis of cervical injury requiring suture repair. #For major complications, this diagnosis includes undetermined diagnoses that required blood transfusions and surgery. For minor complications, the majority of this diagnosis consisted of cases treated with repeat abortion, but the exact diagnosis could not be determined. This category also includes diagnoses such as non-anesthesia-related allergic reactions and seizures. **Major treatments include combinations of treatments including blood transfusion (n=50) and surgery (n=13).

Upadhyay. ED Visits and Complications After Abortion. Obstet Gynecol 2015.

on ED use among patients with public insurance.[11,12] Then, using a standardized methodology for identifying and classifying complications, we estimate the incidence of postabortion complications diagnosed, treated, or diagnosed and treated at all clinical sites to see whether the rate of complications in a closed system with complete follow-up differs from the rates found in other studies.

MATERIALS AND METHODS

We used patient-level billing data from Medi-Cal, California's State Medicaid program. Medi-Cal provides pregnant low-income women immediate, temporary Medicaid coverage. California is one of 17 states that covers abortion and subsequent care for women enrolled in Medicaid. In 2011 an estimated 512 facilities in California performed 181,730 abortions,[1] approximately 51% of which were covered by Medi-Cal.[13]

The study was approved by the institutional review boards of the University of California, San Francisco and the California Health and Human Services Agency.

Medi-Cal is administered on a fee-for-service or managed care arrangement, split approximately in half across the two. Only the fee-for-service billing records contain complete information for care provided to a particular beneficiary; therefore, we received data only for those beneficiaries with fee-for-service coverage. We obtained billing records for every fee-for-service beneficiary who had an abortion

Table 1. Characteristics of Women With Abortions Covered by Medi-Cal, 2009–2010: Abortion-Related Complications, Complication Rates, and Adjusted Relative Risk, by Beneficiary Characteristics

Characteristic	Medi-Cal–Funded Abortions* (N=54,911)	Abortion-Related Complications† (n=1,156)	Abortion-Related Complication Rate/100 Abortions (95% CI)	Adjusted RR‡ (95% CI)	*P*
Age (y)	25.1±6.5				
19 or younger	11,446 (20.8)	173 (15.0)	1.51 (1.30–1.75)	0.87 (0.71–1.07)	.20
20–24	18,051 (32.9)	371 (32.1)	2.06 (1.86–2.27)	Reference	—
25–29	12,481 (22.7)	290 (25.1)	2.32 (2.07–2.60)	1.07 (0.91–1.26)	.40
30–39	11,508 (21.0)	296 (25.6)	2.57 (2.30–2.88)	1.20 (1.02–1.40)	.03
40 or older	1,400 (2.6)	25 (2.2)	1.79 (1.21–2.63)	0.83 (0.55–1.26)	.55
Race or ethnicity					
Non-Hispanic white	12,614 (23.0)	337 (29.1)	2.67 (2.40–2.97)	Reference	—
Non-Hispanic black	7,144 (13.0)	140 (12.1)	1.96 (1.66–2.31)	0.90 (0.73–1.12)	.35
Hispanic	23,110 (42.1)	471 (40.7)	2.04 (1.86–2.22)	0.76 (0.65–0.89)	<.001
Asian	2,771 (5.1)	62 (5.4)	2.24 (1.75–2.86)	0.87 (0.65–1.16)	.34
Other§	2,602 (4.7)	60 (5.2)	2.31 (1.79–2.96)	0.91 (0.68–1.21)	.50
Abortion procedure type					
Medication	11,319 (20.6)	588 (50.9)	5.19 (4.79–5.60)	5.96 (5.11–6.94)	<.001
1st-trimester aspiration	34,755 (63.3)	438 (37.9)	1.26 (1.14–1.38)	Reference	—
2nd trimester or later	8,837 (16.1)	130 (11.2)	1.47 (1.22–1.72)	0.98 (0.79–1.23)	.88
Site of procedure					
Hospital	1,667 (3.0)	84 (7.3)	5.04 (4.09–6.20)	4.74 (3.40–6.61)	<.001
Outpatient clinic	30,778 (56.1)	583 (50.4)	1.89 (1.75–2.05)	Reference	—
Physician's office or group	22,466 (40.9)	489 (42.3)	2.18 (1.99–2.38)	1.70 (1.32–2.17)	<.001
Residence type					
Urban	43,566 (90.5)	935 (80.9)	2.15 (2.01–2.29)	Reference	—
Rural	4,587 (9.5)	132 (11.4)	2.88 (2.43–3.40)	1.23 (1.00–1.52)	.05
Year of abortion					
2009	28,823 (52.5)	559 (48.4)	1.94 (1.79–2.11)	Reference	—
2010	26,088 (47.5)	597 (51.6)	2.29 (2.11–2.48)	1.03 (0.91–1.16)	.69

CI, confidence interval; RR, relative risk.
Data are mean±standard deviation or n (%) unless otherwise specified.
* The unit of analysis is women's abortions; the same woman may be represented more than once here if she had multiple abortions during the study period. Plus–minus values are mean±standard deviation. Data on age were missing for 25 abortions, data on woman's race or ethnicity were missing for 6,670 women, and data on woman's residence type were missing for 6,758 abortions.
† Cases may not add up to 1,156 as a result of missing data.
‡ Adjusted for age, race or ethnicity, abortion procedure type, site of procedure, residence type, and year of abortion.
§ Other includes Alaskan, American Indian, Hawaiian, Samoan, unknown, or other race or ethnicity.

Table 2. Reasons for Emergency Department Visits Within 6 Weeks of Initial Abortion

Characteristic of Visit	Total ED Visits (n=3,531)	Proportion of ED Visits (95% CI)
Reason for visit		
Not abortion-related	1,758	49.8 (48.14–51.44)
Abortion-related	1,431	40.5 (38.92–42.15)
Not abortion-related but concurrent*	332	9.4 (8.48–10.41)
Unknown	10	0.3 (0.15–0.53)
Abortion-related ED visit	1,431	40.5 (38.92–42.15)
Received treatment†	478	33.4 (31.00–35.89)
Did not receive treatment‡	953	66.6 (64.11–69.00)
Abortion procedure type		
Medication	770	21.8 (20.47–23.20)
1st-trimester aspiration	2,266	64.2 (62.57–65.74)
2nd trimester or later	495	14.0 (12.91–15.20)

ED, emergency department; CI, confidence interval.

* These are medical problems that were diagnosed, treated, or diagnosed and treated at the time of the abortion procedure (eg, ectopic or molar pregnancy, preexisting medical condition, or concurrent problems present at the time of the procedure).

† These are cases in which a patient received an abortion-related diagnosis or treatment and therefore were considered a complication.

‡ These are cases in which a patient presented with abortion-related symptoms but did not receive a pathologic diagnosis or treatment (eg, observation only).

in 2009 and 2010 and all billing records for all clinical encounters for each of those beneficiaries up to 6 weeks after the abortion. Each clinical encounter results in multiple ($\bar{x}$=12) billing records; thus, we acquired 659,361 records.

Data included an encrypted beneficiary identification number, date of birth, race or ethnicity, city, state, zip code, date(s) of service, type of facility, diagnosis (International Classification of Diseases, 9th Revision [ICD-9] codes), procedure or treatment (Healthcare Common Procedure Coding System, Current Procedural Terminology [CPT] codes), facility type, and amount paid per treatment. For each abortion, we calculated the beneficiary's age and urban or rural residence (determined by zip code).

Abortions were identified using Healthcare Common Procedure Coding System codes (59840–59841, 59850–59852 and 59855–59857, X7724, Z0336); these codes also indicated the abortion type: 1) "medication abortions," which includes use of mifepristone and misoprostol up to 9 weeks of gestation; 2) "first-trimester aspiration," which includes both manual and electric aspiration abortions as well as dilation and curettage "in the first 12–14 weeks of gestation"[14]; and 3) "second-trimester or later procedures." Included in this latter category are medical and surgical abortions performed using multiple abortion techniques such as dilation and evacuation, with or without osmotic dilators and misoprostol as well as full or partial inductions used "after 12–14 weeks of gestation."[14] The billing data that we had did not allow us to make a determination of weeks of gestation nor the specific technique used.

We searched for additional claims made to MediCal up to 6 weeks after the abortion for each abortion identified. Postabortion ED visits (not including urgent care) within 6 weeks were identified using codes associated with ED use (Healthcare Common Procedure Coding System codes: 99281–99285, and Z7502). Clinically trained reviewers evaluated all available billing data (including all ICD-9 and Healthcare Common Procedure Coding System or CPT procedure codes) for each beneficiary who had an ED visit and assigned the visit to one of three categories: 1) not abortion-related; 2) not abortion-related but for a concurrent problem (diagnosed, treated, or diagnosed and treated at the time of the abortion); and 3) abortion-related. An ED visit was classified as abortion-related based on the constellation of ICD-9

Table 3. Major and Minor Abortion-Related Complication Rates by Procedure Type

	Medication Abortion (n=11,319)		1st-Trimester Aspiration (n=34,755)	
Complication Type	Rate/100 (95% CI)	n	Rate/100 (95% CI)	n
Major	0.31 (0.21–0.41)	35	0.16 (0.12–0.21)	57
Minor	4.88 (4.49–5.28)	553	1.10 (0.99–1.21)	381
Total complications	5.19 (4.79–5.60)	588	1.26 (1.14–1.38)	438

CI, confidence interval.

and Healthcare Common Procedure Coding System or CPT procedure codes for that visit. For example, in many cases, it was a combination of an ICD-9 code for an abortion, postabortion complication, or abdominal pain that indicated that the visit was abortion related along with a Healthcare Common Procedure Coding System or CPT procedure code for a pregnancy test, pelvic examination, transvaginal ultrasonography, abdominal ultrasonography, or dose of misoprostol.

Each abortion-related visit was then classified as 1) woman received an abortion-related diagnosis, treatment, or both; or 2) woman presented with abortion-related symptoms such as abdominal pain or cramping but received no pathologic diagnosis or treatment. When ED visits took place for multiple reasons, only the reason most closely related to the abortion was recorded (Fig. 1).

Additionally, we identified all ambulance transfers (Healthcare Common Procedure Coding System codes: X0030, X0034, X0036, X0400, X0402, X0412) and all self-referred ED visits on the day of the abortion regardless of whether the visit resulted in an abortion-related diagnosis or treatment.

The process of identifying and classifying abortion complications involved several steps. We defined a complication as any postabortion adverse event that received an abortion-related diagnosis or treatment at any source of care, including EDs and the original abortion facility within 6 weeks of an abortion procedure. To identify complications, the clinically trained reviewers evaluated all: 1) abortion-related diagnoses and treatments identified through the ED visit analysis described previously (excluding visits having no pathologic diagnosis or treatment); 2) ICD-9 codes that indicate abortion-related complications (635.00–635.82) and Healthcare Common Procedure Coding System or CPT codes for laparoscopy, laparotomy, and hysterectomy surgeries (49000, 49320, 49329, 58150, 58578, 58960), blood transfusions (86970, P9016–P9021, P9048, 390), and antibiotics commonly used to treat abortion-related infections and sepsis at least 1 day after the abortion; and 3) subsequent medication abortions and aspirations within 6 weeks.

The reviewers examined each case identified through this process and applied a systematic classification scheme developed by several of this study's authors and used in a recent study of abortion safety.[3] The classification system comprised a list of known abortion complications with standard definitions that included specific criteria (signs, symptoms, laboratory findings) to indicate the complication diagnosis. To validate the system, first, outside experts who work with the U.S. Agency for Health Research & Quality Evidence-Based Practice Centers and from abortion-related research or service delivery reviewed the classification system. Second, a Data and Clinical Safety Monitoring Committee reviewed incident data to further clarify complication definitions and criteria.

For this study, the clinician reviewers categorized each identified case into one of seven diagnoses: incomplete abortion, failed abortion, hemorrhage, infection, uterine perforation, anesthesia-related, and other or undetermined. The clinically trained reviewers examined all available billing data for the beneficiary, including laboratory tests ordered and medications, to validate each diagnosis. For example, to confirm a diagnosis of failed abortion, they checked for additional confirmatory evidence such as codes for aspiration or prenatal care. For diagnoses of hemorrhage, the reviewers looked for treatments such as aspiration, Methergine, or blood transfusion. One diagnosis category was assigned per abortion; when the billing records indicated more than one diagnosis, the highest level diagnosis was selected. Cases identified based on subsequent medication abortion, misoprostol dose, or aspiration within 6 weeks of the initial abortion without any ICD-9 code indicating a complication were categorized as "other or undetermined."

2nd Trimester or Later (n=8,837)		Total (N=54,911)		*P*	
Rate/100 (95% CI)	n	Rate/100 (95% CI)	n	Medication Abortion vs 1st-Trimester Abortion	1st-Trimester Abortion vs 2nd Trimester or Later
0.41 (0.27–0.54)	36	0.23 (0.19–0.27)	126	.003	<.001
1.09 (0.87–1.30)	96	1.88 (1.76–1.99)	1,030		
1.47 (1.22–1.72)	130	2.11 (1.99–2.23)	1,156	<.001	.12

Table 4. Distribution of Abortion-Related Complication Diagnoses by Type of Procedure and Type of Treatment

Characteristic	Complication Diagnosis			
	Incomplete Abortion	Failed Abortion	Hemorrhage	Infection
Abortion procedure type[‡]				
Medication abortion (11,319)	99 (0.87)	15 (0.13)	16 (0.14)	26 (0.23)
1st-trimester aspiration (34,755)	116 (0.33)	14 (0.04)	44 (0.13)	94 (0.27)
2nd trimester or later (8,837)	16 (0.18)	1 (0.01)	26 (0.29)	18 (0.20)
Total (54,911)	231 (0.42)	30 (0.05)	86 (0.16)	138 (0.25)
Type of treatment[§]				
No treatment	0 (0.00)	5 (16.67)	0 (0.00)	0 (0.00)
Medication	2 (0.87)	0 (0.00)	20 (23.27)	100 (72.46)
Uterine aspiration	198 (85.71)	22 (73.33)	22 (25.58)	8 (5.80)
Both medication and aspiration	18 (7.79)	0 (0.00)	5 (5.81)	8 (5.80)
Other[‖]	13 (5.63)	3 (10.00)	34 (39.53)	6 (4.35)
Undetermined	0 (0.00)	0 (0.00)	5 (5.81)	16 (11.59)
Total	231 (100.0)	30 (100.0)	86 (100.0)	138 (100.0)

Data are n (%).
* Includes one diagnosis of cervical injury requiring suture repair.
† For major complications, this diagnosis includes undetermined diagnoses that required blood transfusions and surgery. For minor complications, the majority of this diagnosis consisted of cases treated with repeat abortion, but the exact diagnosis could not be determined. This category also includes diagnoses such as nonanesthesia-related allergic reactions and seizures.
‡ Row percentages reported.
§ Column percentages reported.
‖ Includes treatments such as blood transfusion (n=50 for major complications), surgical repair (n=13 for major complications), and tamponade.

Cases with the ICD-9 code "635.8 Abortion with unspecified complication" were also categorized as other or undetermined. To produce the most conservative estimate, we included undetermined diagnoses in the overall complications estimate.

Each complication was then classified as receiving one of six treatment categories: no treatment, medication (including mifepristone and misoprostol, misoprostol alone, or other medications), uterine aspiration, both medication and aspiration, other treatment, or undetermined. Abortion-related complications were classified as major if they required hospital admission (vendor codes 50, 60), surgery, or blood transfusion with all others classified as minor.

The data analysis was done in several steps. Using Stata 13, first we described the sample characteristics: age, race, residence, abortion procedure type, facility type, and year of abortion. Second, we estimated ED visits on the day of the abortion and within 6 weeks and present reasons for visits. Third, we estimated the abortion-related complication rate by the sample characteristics and the relative risk of a complication adjusted for all other characteristics using a generalized linear mixed model that accounts for lack of independence between multiple abortions by the same woman and those performed by the same health care provider; *P* values were determined from z tests derived from the model. Women who had missing data for any characteristic were retained in the model. Fourth, we compared major and minor complications by abortion procedure type using Pearson χ^2 tests. Finally, we described complication diagnoses by abortion procedure type and treatment. The abortion was the unit of analysis because 8.3% (n=4,165) of women in the data set had more than one abortion. Statistical significance was set at $P<.05$ for all comparisons; 95% confidence intervals (CIs) are reported.

RESULTS

Among the 659,361 records received, we identified 54,911 abortions among 50,273 fee-for-service Medi-Cal beneficiaries in 2009 and 2010. The largest proportions of women were ages 20–29 years, Hispanic, urban, had undergone first-trimester aspiration abortion, and were seen at an outpatient clinic (Table 1).

Among all 54,911 abortions, one in 1,036 (0.10%, n=53) were followed by an ED visit on the day of the abortion, including 1 of 5,491 (0.03%, n=15) transferred by ambulance for immediate care, although not all resulted in an abortion-related diagnosis or treatment.

Among all abortions (N=54,911), 1 of 16 (6.4%, n=3,531) was followed by an ED visit within 6 weeks of the abortion. Of these, 49.8% (n=1,758) were

Complication Diagnosis			
Uterine Perforation*	Anesthesia-Related	Other or Undetermined†	Total (N=54,911)
0 (0.00)	0 (0.00)	432 (3.82)	588 (5.19)
2 (0.01)	2 (0.01)	166 (0.48)	438 (1.26)
7 (0.08)	2 (0.02)	60 (0.68)	130 (1.47)
9 (0.02)	4 (0.01)	658 (1.20)	1,156 (2.11)
1 (11.11)	0 (0.00)	22 (3.34)	28 (2.42)
0 (0.00)	4 (100.0)	205 (31.16)	331 (28.63)
0 (0.00)	0 (0.00)	400 (60.79)	650 (56.23)
0 (0.00)	0 (0.00)	2 (0.30)	31 (7.44)
5 (55.56)	0 (0.00)	23 (3.50)	86 (2.68)
3 (33.33)	0 (0.00)	6 (0.91)	30 (2.60)
9 (100.0)	4 (100.0)	658 (100.0)	1,156 (100.0)

unrelated to the abortion, 9.4% (n=332) were conditions unrelated to but concurrent with the abortion, and 40.5% (n=1,431) were abortion-related. Among abortion-related visits, two thirds (66.6%, n=953) were cases in which a patient presented with abortion-related symptoms but did not receive a pathologic diagnosis or treatment. Thus, 1 of 115 (0.87%, n=478) abortions resulted in an ED visit receiving a diagnosis, treatment, or diagnosis and treatment. Among all abortion-related ED visits (n=1,431), 21.8% (n=770) followed a medication abortion, 64.2% (n=2,266) followed a first-trimester aspiration abortion, and 14.0% (n=495) followed a second-trimester or later procedure (Table 2).

Among all abortions (N=54,911), 1,156 (2.1%, 95% CI 1.99–2.23) resulted in an abortion-related complication diagnosed or treated at any source of care, including EDs and the original abortion facility. The unadjusted complication rate was 5.2% (n=588) for medication abortions, 1.3% (n=438) for first-trimester aspiration abortions, and 1.5% (n=130) for second-trimester or later procedures. Adjusted results indicate that women ages 30–39 years were 1.20 (95% CI 1.02–1.40) times as likely to have a complication compared with women ages 20–24 years, and Hispanic women were significantly less likely to have a complication compared with white women. Medication abortions were 5.96 (95% CI 5.11–6.94) times as likely to result in a complication as first-trimester aspiration abortions. Women receiving abortion care at hospitals or physician's offices or groups were significantly more likely to have a complication than women receiving care at outpatient clinics (Table 1).

The rate of major complications among all 54,911 abortions was 0.23% (95% CI 0.19–0.27) (n=126, 1/436), 0.31% (n=35) among women who had medication abortions, 0.16% (n=57) among women who had first-trimester aspiration abortions, and 0.41% (n=34) among women who had second-trimester or later procedures (Table 3). Among all women, 0.20% (n=108) were admitted to hospitals, 0.02% (n=13) had surgery, and 0.09% (n=50) received blood transfusions (data not shown). These three categories are not mutually exclusive; some women were admitted to a hospital and had surgery, received a blood transfusion, or had surgery and a blood transfusion.

The most common complications were other or undetermined diagnoses (1.20%, n=658), comprised mostly of undetermined diagnoses that lead to repeat abortion, and incomplete abortions (0.42%, n=231) (Table 4). The majority of incomplete abortions (85.7%, n=198) and failed abortions (73.3%, n=22) were treated with uterine aspiration. The majority of hemorrhage cases were treated by other treatments (including blood transfusion) (39.5%, n=34) or medication (23.3%, n=20). All anesthesia-related cases were treated with medication as were the majority of infections (72.5%, n=100).

DISCUSSION

We observed a 2.1% abortion-related complication rate after nearly 55,000 abortions diagnosed or treated at all sources of care. The majority were minor. Rates of transfers to an ED, hospital admissions, surgeries, and blood transfusions were low. The complication rate is much lower than that found during childbirth[15] and comparable to that found in the literature[3,7] even when ED visits are included and there is no loss to follow-up.

We observed the highest rate of complications among women obtaining medication abortions (5.2%, n=588), the vast majority of which were minor and expected. This rate may be overestimated with aspirations performed presumptively or to alleviate bleeding or cramping symptoms.[16] Nevertheless, this rate is consistent with intervention rates found in other studies.[17,18]

The complication rate for second-trimester or later procedures is lower than other studies.[4,19] This may be because the second-trimester or later category includes a large number of abortions performed earlier in the second trimester when complication rates are closer to those in the first trimester. Only 1.4% of all abortions nationally occur after 20 weeks of gestation[20]; our data should not be used to make determinations about the complication rate among the small number of procedures performed later in pregnancy.

We found a high rate (6.4%) of ED visits after abortion, half of which were not abortion-related. This finding is consistent with previous research and could reflect Medi-Cal beneficiaries' use of the ED as the health care provider of first resort.[11] Additionally, the Medi-Cal fee-for-service population has been noted as having greater health risks and more costly use compared with the Medi-Cal managed care population.[21]

Two thirds of abortion-related ED visits did not result in a diagnosis or treatment, representing visits primarily for symptoms, not complications. Strategies to reduce ED visits include increasing the number and types of Medi-Cal primary care providers, particularly in underserved areas, who can provide abortion care, postabortion care, or both, and improving health care provider–patient communication on nonurgent postprocedure side effects.

This study examines postabortion ED visits and complications up to 6 weeks and across multiple facilities without loss to follow-up, addressing a common methodologic limitation of other studies. In other studies, follow-up periods ranged from 2 to 4 weeks with most considering follow-up a return visit to the original abortion facility. When reported, loss to follow-up varies widely: 9% at 1 week,[7] 2–34% at 2 weeks,[5,8,9] and between 8 and 65% in studies where duration is not specified.[22,23] Additionally, this study has the sample size necessary to robustly estimate rare events.

Using billing codes to identify complications has methodologic limitations. Administrative data sets often contain erroneous codes[24]; however, our clinical reviewers examined all related billing records for patients with complications for inconsistencies and errors. Also, by relying on Medi-Cal codes, we could not assess whether any of the complications lead to deaths or detect complications not documented by billing codes. It is possible that complications seen or treated at the original abortion facility did not result in any Medi-Cal reimbursements, thereby underestimating the complication rate.

We were unable to determine the exact week of gestation of each abortion, which is known to be a strong predictor of complication risk.[6] Additionally, repeat abortions performed within 6 weeks were assumed to be for the same pregnancy, but they may have been for new pregnancies. This, too, may lead to overestimating the complication rate, although the proportion of new pregnancies is likely too small to have much effect.

Regarding generalizability to the national abortion population, demographically, our sample had higher rates of Hispanics, lower rates of blacks,[25] and presumably higher rates of low-income women. Medi-Cal beneficiaries may have more health problems than the general population[21] and given that the sample had insurance coverage, they may differ from women whose follow-up care is self-pay. These differences would mean that the reported complication rate is overestimated.

These new data can inform policy debates regarding abortion regulation in the United States. State legislatures have passed regulations such as ambulatory surgical center requirements (23 states), transfer agreement laws (eight states), and hospital admitting privileges requirements (13 states)[26] with the stated intent to increase safety. Given that in practice their ultimate effect often is the closure of abortion facilities,[27] there is a need to consider the public health effect of these policies, weighing any theoretical incremental reduction in patient risk that may occur against any increases in risk that may occur with reduced access to abortion care.

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Exhibit 1-8

Centers for Disease Control and Prevention

Coronavirus Disease 2019

Pregnancy and Breastfeeding

We do not currently know if pregnant people have a greater chance of getting sick from COVID-19 than the general public nor whether they are more likely to have serious illness as a result. Based on available information, **pregnant people seem to have the same risk as adults who are not pregnant**.

However, we do know that

- Pregnant people have changes in their bodies that may increase their risk of some infections.
- Pregnant people have had a higher risk of severe illness when infected with viruses from the same family as COVID-19 and other viral respiratory infections, such as influenza.

Pregnant people should protect themselves from COVID-19

- Avoid people who are sick or who have been exposed to the virus.
- Clean your hands often using soap and water or alcohol-based hand sanitizer.
- Clean and disinfect frequently touched surfaces daily.

Risks to the pregnancy and to the baby

- Pregnant people have had a higher risk of severe illness when infected with viruses from the same family as COVID-19 and other viral respiratory infections, such as influenza.
- It is always important for pregnant people to protect themselves from illnesses.

Mother-to-child transmission

- Mother-to-child **transmission of coronavirus during pregnancy is unlikely, but after birth a newborn is susceptible to person-to-person spread.**
- A very small number of babies have tested positive for the virus shortly after birth. However, it is unknown if these babies got the virus before or after birth.
- The virus has not been detected in amniotic fluid, breastmilk, or other maternal samples.

Breastfeeding if you have COVID-19

- **Breast milk provides protection against many illnesses** and is the best source of nutrition for most infants.
- You, along with your family and healthcare providers, should decide whether and how to start or continue breastfeeding
- **In limited studies, COVID-19 has not been detected in breast milk**; however we do not know for sure whether mothers with COVID-19 can spread the virus via breast milk.

- If you are sick and choose to **direct breastfeed**:
  - Wear a facemask and wash your hands before each feeding.
- If the you are sick and choose to **express breast milk**:
  - Express breast milk to establish and maintain milk supply.
  - A dedicated breast pump should be provided.
  - Wash hands before touching any pump or bottle parts and before expressing breast milk.
  - Follow recommendations for proper pump cleaning after each use, cleaning all parts that come into contact with breast milk.
  - If possible, consider having someone who is well feed the expressed breast milk to the infant.

Related: How to Protect Yourself

Page last reviewed: April 3, 2020

Exhibit 1-9

ACOG
The American College of Obstetricians and Gynecologists

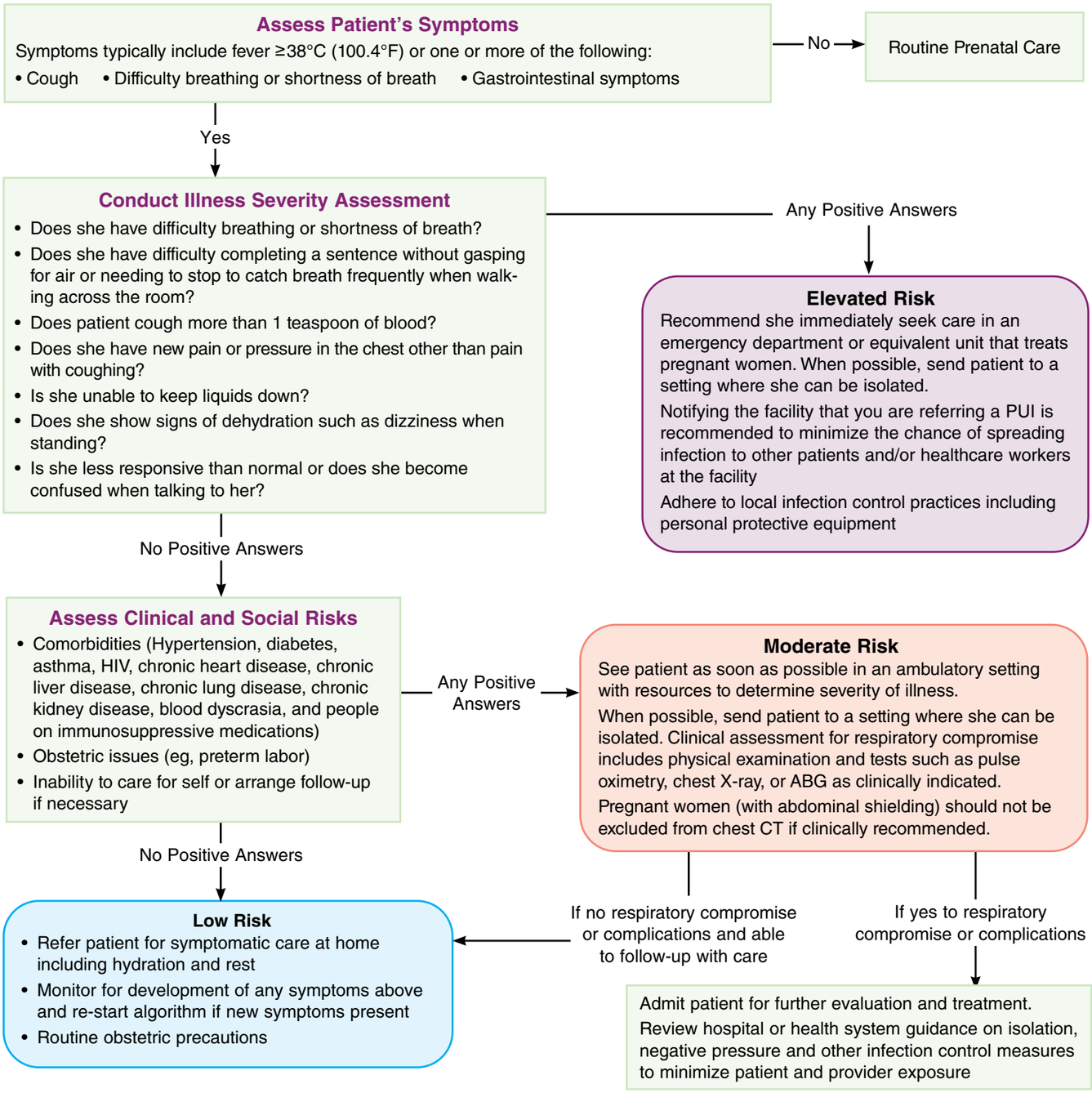
Society for Maternal-Fetal Medicine
High-risk pregnancy experts

Outpatient Assessment and Management for Pregnant Women With Suspected or Confirmed Novel Coronavirus (COVID-19)

Historically, pregnant individuals have been thought to be at increased risk of severe morbidity and mortality from specific respiratory infections. With regard to COVID-19, the limited data currently available do not indicate that pregnant individuals are at an increased risk of infection or severe morbidity (eg, need for ICU admission or mortality) compared with nonpregnant individuals in the general population. Pregnant patients with comorbidities may be at increased risk for severe illness consistent with the general population with similar comorbidities. To date, consistent with our experience with other respiratory viruses such as MERS, SARS, and influenza, there is no conclusive evidence of vertical transmission of COVID-19. ACOG will continue to diligently monitor the literature for any COVID-19 risk signals in pregnancy.

This algorithm is designed to aid practitioners in promptly evaluating and treating pregnant persons with known exposure and/or those with symptoms consistent with COVID-19 (persons under investigation [PUI]). If influenza viruses are still circulating, influenza may be a cause of respiratory symptoms and practitioners are encouraged to use the ACOG/SMFM influenza algorithm to assess need for influenza treatment or prophylaxis.

Please be advised that COVID-19 is a rapidly evolving situation and this guidance may become out-of-date as new information on COVID-19 in pregnant women becomes available from the Centers for Disease Control and Prevention (CDC). https://www.cdc.gov/coronavirus/2019-nCoV/index.html. ACOG COVID page: https://www.acog.org/topics/covid-19



Abbreviations: ABG, arterial blood gases; CDC, Centers for Disease Control and Prevention; HIV, human immunodeficiency virus.

Healthcare providers should immediately notify their local or state health department in the event of a PUI for COVID-19 and should contact and consult with their local and/or state health department for recommendations on testing PUIs for COVID-19.

Exhibit 1-10

Upadhyay et al. BMC Medicine (2018) 16:88
https://doi.org/10.1186/s12916-018-1072-0

BMC Medicine

RESEARCH ARTICLE Open Access

Abortion-related emergency department visits in the United States: An analysis of a national emergency department sample

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Abstract

Background: Media depictions and laws passed in state legislatures regulating abortion suggest abortion-related medical emergencies are common. An accurate understanding of abortion-related emergencies is important for informing policy and practice. We assessed the incidence of abortion-related emergency department (ED) visits in the United States (U.S.).

Methods: We used a retrospective observational study design using 2009–2013 data from the Nationwide Emergency Department Sample, a nationally representative sample of U.S. ED visits from 947 to 964 hospitals across the U.S. per year. All ED visits among women of reproductive age (15–49) were included. We categorized ED visits by abortion relatedness and treatments received, and assessed whether the visit was for a major incident (defined as requiring blood transfusion, surgery, or overnight inpatient stay). We estimated the proportion of visits that were abortion-related and described the characteristics of patients making these visits, the diagnoses and subsequent treatments received by these patients, the sociodemographic and hospital characteristics associated with the incidents and observation care only (defined as receiving no treatments), and the rate of major incidents for all abortion patients in the U.S.

Results: Among all ED visits by women aged 15–49 (189,480,685), 0.01% ($n = 27,941$) were abortion-related. Of these visits, 51% (95% confidence interval, 95% CI 49.3–51.9%) of the women received observation care only. A total of 20% (95% CI 19.3–21.3%) of abortion-related ED visits were for major incidents. One-fifth (22%, 95% CI 20.9–23.0%) of abortion-related visits resulted in admission to the same hospital for abortion-related reasons. Of the visits, 1.4% ($n = 390$, 95% CI 1.1–1.7%) were potentially due to attempts at self-induced abortion. In multivariable models, women using Medicaid (adjusted odds ratio, AOR 1.28, 95% CI 1.08–1.52) and women with a comorbid condition (AORs 2.47–4.63) had higher odds of having a major incident than women using private insurance and those without comorbid conditions. During the study period, 0.11% of all abortions in the U.S. resulted in major incidents as seen in EDs.

Conclusions: Abortion-related ED visits comprise a small proportion of women's ED visits. Many abortion-related ED visits may not be indicated or could have been managed at a less costly level of care. Given the low rate of major incidents, perceptions that abortion is unsafe are not based on evidence.

Keywords: Abortion, Emergency department, Emergencies, Hospital admission, Complications, Health policies

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Background

Emergency departments (EDs) are key sites of health-care delivery in the United States (U.S.), with 141.4 million visits in 2014 alone [1], and 55% of these visits are made by women. Although abortion-related complications are rare [2], the surge in legislation aimed at regulating abortion access [3] suggests that complications are common and that abortion is generally unsafe.

Since 2011, state legislatures across the U.S. have passed numerous laws that regulate abortion provision, many requiring abortion providers to obtain local hospital admitting privileges and have transfer agreements with nearby hospitals [3]. These laws are passed under a presumption that they are needed to protect women's health and safety [4, 5] and that hospitalization as a result of abortion is an occurrence frequent enough to necessitate legislation formalizing the relationship between hospitals, abortion providers, and clinics.

National-level estimates of abortion-related ED visits do not exist. However, data from one state suggests that abortion-related ED visits are rare. In a study using data from California's Medicaid program, Upadhyay et al. found that 0.03% of abortions were followed by an immediate ambulance transfer to an ED and 2.6% of abortions were followed by an abortion-related ED visit within 6 weeks of the abortion [2]. Another study that examined all medication abortions done by Planned Parenthood in 2009 and 2010 found an ED treatment rate of 0.10%, although medication abortions represented only about 23% of abortions at the time, and this study included only those ED visits that involved treatment [6]. In a study of outcomes of abortion procedures by family physicians in New York and Philadelphia, 0.3% of first-trimester medication and aspiration abortion patients were referred or went to an ED for assessment [7].

There is a paucity of published national data on the incidence and outcomes of ED visits after abortion. In this study, we examine the frequency of abortion-related ED visits, the frequency of major abortion-related incidents, and the characteristics of abortion-related ED visits in the U.S. using a nationally representative sample of ED visits.

Methods

Study design and data source

We conducted a retrospective observational study of abortion-related ED visits using data from the Nationwide Emergency Department Sample (NEDS), a nationally representative sample of ED visits. NEDS is a database of ED visits from 947 to 964 hospitals across the U.S. per year. Annually it includes more than 30 million unweighted visits, which represent more than 135 million weighted visits. NEDS was developed for the Healthcare Cost and Utilization Project (HCUP) and is maintained by the Agency for Healthcare Research and Quality. Data are available from 2006 onward. For this study, we utilized the five most recent years of data available (2009–2013). The study was certified exempt by the institutional review board of the University of California, San Francisco.

Unweighted visits are data collected on actual visits, which are then weighted proportionately to the total number of ED visits in the country based on the sampling strategy. The NEDS is a stratified single-stage cluster sample of state-level ED data reported to HCUP. Using the American Hospital Association Annual Survey of Hospitals as the target universe, the available data are selected to approximate a 20% stratified sample of all U.S. hospital-based EDs. More details of the sampling of hospitals can be found on the HCUP website [8, 9]. The characteristics used for sample stratification in the NEDS are U.S. region, urban or rural location, teaching status, ownership, and trauma level (see Fig. 1 for region definitions and states contributing data).

The NEDS includes patient-level and hospital-level information. Each ED visit has patient-level demographic characteristics including age, sex, primary and secondary payment source, and zip code-based urbanicity and income quartile. Each ED visit also has clinical characteristics, including up to 15 diagnoses (International Classification of Diseases, 9th Revision [ICD-9] codes), up to 15 procedures or treatments (Healthcare Common Procedure Coding System [HCPCS] and Current Procedural Terminology [CPT] codes), injury codes, admission and discharge status, diagnosis and treatment codes for inpatient care if admitted to the same hospital, and total charges. Each visit also has the corresponding hospital code, and hospital characteristics such as region, trauma level, urban-rural location, and teaching status. In this dataset, 5 of 13 states in the West, 11 of 12 states in the Midwest, 8 of 16 states in the South, and 8 of 9 states in the Northeast were represented in the data. Midwest hospitals were represented the most. The trauma level of a hospital refers to how well equipped it is to provide care to patients with traumatic injuries. Trauma level influences patient composition and was key to sample stratification in the dataset. Hospital ownership was categorized by the data distributor according to information reported in the American Hospital Association Annual Survey Database. Ownership could be governmental, private non-profit, or private for-profit. Hospitals with religious affiliations, including Catholic hospitals, are included, but are not distinguished as such and may fall into private for-profit or private non-profit categories. Federal hospitals (Veterans Affairs and Department of Defense) were not included in the sample. Patient-level and hospital-level weights were also provided to generate nationally representative estimates. HCUP provided weights for the NEDS data and these

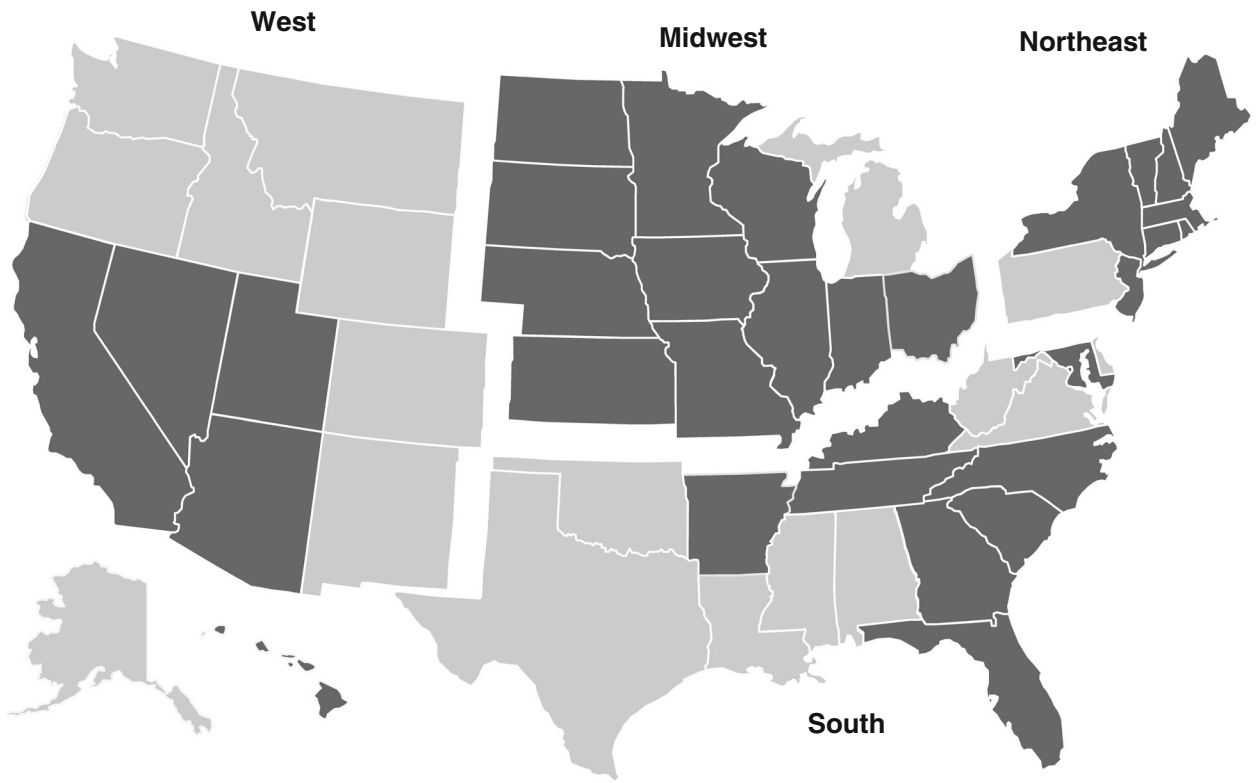

Fig. 1 U.S. regions in the National Emergency Department Sample. States in darker shades contributed data to the National Emergency Department Sample during the study period, 2009–2013

were calculated at the hospital level after sampling by hospital strata. Patient weights were calculated first by stratifying the data by hospital characteristics (region, urbanicity, trauma level, teaching status, and ownership). Within each of these strata, a weight was generated by dividing the total number of ED visits in the U.S. in that year for that stratum (from American Hospital Association data) by the number of ED visits for that stratum in the NEDS data. Weighted data thus represent all ED visits in the U.S. for a year.

Data preparation

We identified all ED visits that had an ICD-9 diagnosis code for abortion (ICD-9 diagnosis codes 635, 636, 637, and 638). We categorized ED visits by abortion relatedness and treatments received, and assessed whether the visit was for a major or minor incident. Visit categorization was based on the previously developed Procedural Abortion Incident Reporting and Surveillance (PAIRS) Framework [10]. Based on procedure codes, visits that were for observation care, repeat procedures (codes present in the dataset were CPT/HCPCS procedure codes 59812, 59820, 59821, 59840, 59841, 59851, 59855, and 59856; and ICD-9 procedure codes 6901, 6902, 6909, 6951, 6952, 6959, 734, and 750), blood transfusions (CPT/HCPCS procedure codes 36430 and P9021; and ICD-9 procedure codes 9903–9905), and abortion-related surgeries (CPT/HCPCS procedure codes 49320, 58662, 58999, 59300, and 59898; and ICD-9 procedure codes 680, 6831, 6839, 6849, 6851, 6859, 6869, and 7491) were systematically coded without individual visit review. Where procedure and diagnosis codes for a visit did not fall into one of these categories, several authors who are emergency medicine physicians or students with physician supervision provided an individual review of each visit following a modified version of the PAIRS framework (see Fig. 2). After a joint review of 100 visits with refinement of the decision rules, the physicians reviewed the remaining uncategorized visits, resulting in 1642 reviewed ED visits in total.

For each reviewed visit, the emergency medicine physicians assigned the reason for the patient's ED visit to one of five categories: abortion-related, concurrent condition, pre-existing condition, not abortion-related, or cannot determine. They classified an ED visit as abortion-related based on the constellation of diagnosis and procedure codes for that visit. Abortion-related visits included adverse events, such as hemorrhage or infection, and symptoms directly related to the procedure, such as abdominal pain and vomiting. Concurrent conditions were defined as

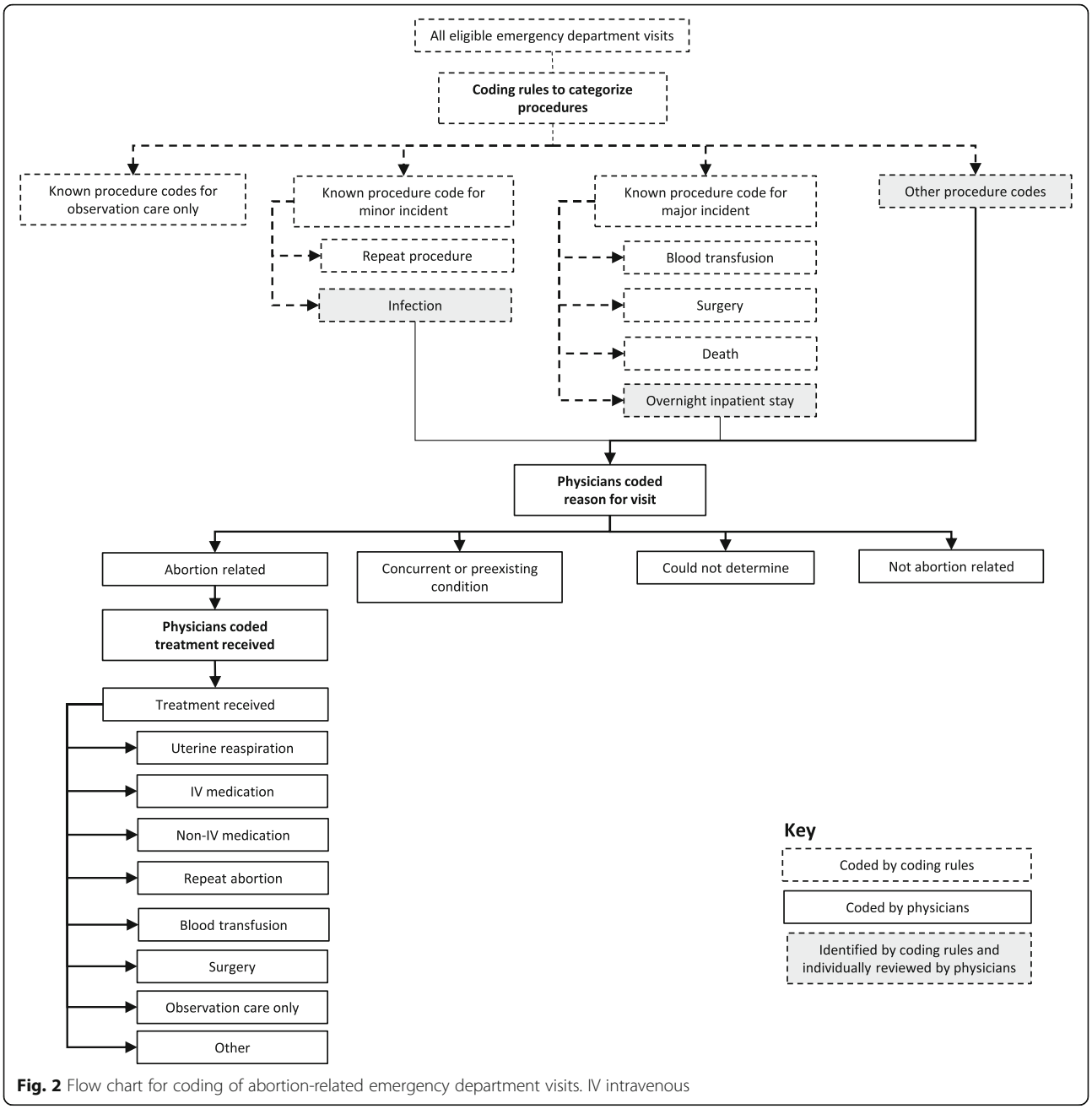

Fig. 2 Flow chart for coding of abortion-related emergency department visits. IV intravenous

conditions that may have been noticed during or exacerbated by abortion, but were not directly caused by the abortion, such as ovarian cysts, vaginitis, urinary tract infection, or anxiety/depression. Pre-existing conditions were defined as chronic conditions such as hypertension or diabetes. The data were also categorized with regards to treatments received for abortion-related complaints. Categories of treatment included uterine reaspiration (which involves suction, not an incision, and does not meet the criteria for surgery), intravenous (IV) and non-IV medication, repeat abortion, blood transfusion, surgery, observation care, or other. The medication category excluded codes for injections or infusion of a therapeutic substance if no accompanying medication was listed. The observation care category included women who had routine testing for their symptoms but did not receive any medications or other treatments. This included women who had IV fluids, blood work, testing for sexually transmitted infections, and diagnostic imaging studies, but no treatments. The NEDS dataset also included information on whether patients were admitted as an inpatient to the same hospital, discharged home, transferred to another facility, or left against medical advice. Among women who were admitted, the reason for visit

and treatment information in their chart was used to determine if the admission was likely abortion-related.

Major and minor incidents were systematically coded, with major incidents defined as those requiring an overnight inpatient stay, blood transfusion, or surgery. Minor incidents were defined as all other incidents that involved an abortion-related diagnosis or treatment. All overnight stays were further reviewed by physicians, and a group of treatments for an abortion-related diagnosis that together required the patient to stay overnight qualified as a major incident. Visits that involved concurrent conditions, pre-existing conditions, or visits that were not abortion-related were categorized as no incident. We identified the prevalence of comorbid conditions based on diagnosis codes. These included three key conditions hypothesized to be associated with abortion-related adverse events: diabetes, hypertension, and having an overweight/obese body mass index (BMI) [11–14].

ED visits were additionally categorized as being potentially indicative of a self-induced abortion. The physician team individually reviewed all abortion-related visits that had diagnosis codes of illegal abortion, failed attempted abortion, and certain injury codes (including poisonings and indications of self-harm). They looked at all of the diagnosis codes for that case and made a clinical judgement based on the group of codes together and their ED experience. Visits that were coded as illegal abortions, particularly those that included injury codes, were more often considered potentially self-induced. In addition, visits that included injury codes consistent with self-induction were categorized as such. Cases which were unlikely to have been abortion-related were removed.

Statistical analysis

We estimated the number of abortion-related ED visits annually in the U.S. and the proportion of ED visits among women of reproductive age (15–49) that were for abortion-related care. We examined the characteristics of the sample and compared these to published estimates of the characteristics of abortion patients [15]. We also described outcomes including treatments received and discharge status. Based on treatments received, ED visits were categorized as being for a major incident, a minor incident, no incident, or that the incident type could not be determined. We then built multivariable logistic regression models to examine the factors associated with major incidents and observation care, controlling for sociodemographic characteristics, comorbidities, and hospital characteristics with the ED visit as the unit of analysis. Per the recommendation of the HCUP, the organization which oversees the NEDS database, sample weights were not used in the multivariable models [16]. We also estimated the proportion of ED visits that were potentially due to attempted self-induced abortion. Because the weighted estimates are nationally representative, we were also able to use published national estimates of abortion incidence [17] to estimate the major incident rate for abortion in the U.S. during the study period. This assumes that the vast majority of major incidents go through an ED evaluation (although we acknowledge that a small percentage do not). For all analyses, we report weighted results unless otherwise specified. Where data were missing, a missing category was retained for all analyses. Statistical significance was set at $P < 0.05$ for all chi-squared tests and adjusted odds ratios (AORs). We used STATA 14 for all analyses.

Results

Among 42,493,214 unweighted visits among women of reproductive age (15–49) during the study period, 6342 visits had an abortion diagnosis. Among these, 70 visits were determined to be unrelated to abortion based on clinician review and 33 visits were duplicates (all variables were identical other than ID number); these 103 visits were excluded, leaving an analytical sample of 6239 unweighted abortion-related ED visits. We did not include an additional 101 visits with abortion diagnoses for women outside the age range of interest (younger than 15 or older than 49).

The final analytical sample corresponded to 27,941 weighted ED visits for abortion-related reasons among 189,480,685 weighted ED visits among women of reproductive age. Thus abortion-related ED visits represented 0.01% of all ED visits among women of reproductive age during the study period. All subsequent results are weighted.

The average age of the population seeking abortion-related ED care was 26, and 12.9% of visits were by women under 20 (Table 1). Women using Medicaid were most common (45.2% of visits), followed by those using private insurance (31.4%), and those who self-paid (17.1%). The population seeking abortion-related ED care was overwhelmingly of urban residence (91.0%). Low-income zip code residences were overrepresented in the sample; 27.5% of women lived in a zip code with the lowest national income quartile, while 20.5% lived in the highest income quartile. Comorbid conditions including diabetes (1.5%), hypertension (3.2%), and overweight/obese BMI (1.8%) were noted in abortion-related ED visits. Hospitals in the South (35.5%) and West (31.7%) had the largest number of abortion-related ED visits. Most visits were to non-trauma or trauma level III hospitals (62.8%) and most were to hospitals in urban locations (92.3%). Visit numbers remained approximately constant throughout the study period. Average ED costs were $4719, with 8.6% of ED visits costing $10,000 or more.

Table 1 Characteristics of abortion-related emergency department visits, 2009–2013 weighted *n* = 27,941

	Weighted *N*	Weighted %	Abortion patients in the U.S., 2014% [15]
Total	27,941	100	100
Patient characteristics			
Age			
15–19	3605	12.9	11.7
20–24	9686	34.7	33.6
25–29	6952	24.9	26.5
30–39	6809	24.4	25.0
40–49	888	0.3	3.1
Primary payer			
Private insurance	8787	31.4	31.3
Medicaid	12,624	45.2	34.6
Medicare	410	1.5	–
Self-pay	4764	17.1	27.6[A]
No charge	188	0.7	–
Other	1049	3.8	6.5[B]
Missing	118	0.4	–
Urban/rural residence			
Urban	25,435	91.0	
Rural	2401	8.6	
Missing	104	0.4	
Zip code-based national income quartile			
First quartile (low)	7686	27.5	65.3[C]
Second quartile	7014	25.1	
Third quartile	7082	25.3	21.7
Fourth quartile (high)	5721	20.5	
Missing	437	1.6	13.0
Comorbidities			
Diabetes	415	1.5	
Hypertension	879	3.1	
Overweight/obese BMI	507	1.8	
Hospital characteristics			
Region			
Northeast	4539	16.2	
Midwest	4627	16.6	
South	9912	35.5	
West	8862	31.7	
Trauma level of hospital			
Level I or II	9429	33.7	
Nontrauma or level III	17,537	62.8	
Not specified	974	3.5	
Urban/rural location of hospital			
Urban	25,796	92.3	
Rural	2145	7.7	
Visit characteristics			
ED visit day			
Weekday	20,640	73.9	
Weekend	7301	26.1	
ED visit season			
Fall	5628	20.1	
Winter	5989	21.4	
Spring	6343	22.7	
Summer	6174	22.1	
Missing	3808	13.6	
Year			
2009	5350	19.1	
2010	5899	21.1	
2011	5448	19.5	
2012	5627	20.1	
2013	5617	20.1	
Total ED charges			
<$1000	2643	9.5	
$1000–$1999	4290	15.4	
$2000–$4999	7188	25.7	
$5000–$9999	3083	11.0	
$10,000+	2407	8.6	
Missing	8330	29.8	

BMI body mass index, *ED* Emergency department
[A]Defined as no coverage
[B]Defined as had either insurance through Healthcare.gov or a different type of insurance
[C]Defined as poor (<100% federal poverty level) or low income (<200% federal poverty level). At the time of the study, the national income median was approximately equal to 200% federal poverty level

Half of abortion-related visits received observation care only (50.6%, 95% confidence interval, 95% CI 49.3–51.9%) (Table 2). Nearly a third of visits resulted in a uterine reaspiration or repeat abortion procedure (32.2%, 95% CI 31.0–33.4%). Medications were used in 16.1% of ED visits (95% CI 15.2–17.1%): IV-medications in 13.7% of visits and non-IV medications in 7.4% of visits. The most commonly administered medication was pain medication (10.4%, 95% CI 9.7–11.2%), followed by anti-nausea medication (7.4%, 95% CI 6.8–8.1%) and antibiotics (3.2%, 95% CI 2.8–3.7%). A minority of ED visits involved blood transfusion (5.0%, 95% CI 4.5–

Table 2 Diagnoses and treatments received, weighted $n = 27,941$

	Weighted *N*	Weighted percentage	Weighted percentage 95% confidence interval
Incident type			
Minor incident[A]	10,089	36.1	34.9–37.4
Major incident[B]	5673	20.3	19.3–21.3
No incident	16,087	57.6	56.3–58.8
Could not be determined	426	1.5	1.2–1.9
Treatment received			
Repeat abortion or uterine reaspiration	8994	32.2	31.0–33.4
IV medications	3838	13.7	12.9–14.6
Non-IV medications	2072	7.4	6.8–8.1
Unspecified type medication	232	0.8	0.6–1.1
Type of medication			
Pain	2912	10.4	9.7–11.2
Nausea	2080	7.4	6.8–8.1
Antibiotics	895	3.2	2.8–3.7
Other	1361	4.9	4.3–5.5
Blood transfusion	1397	5.0	4.5–5.6
Surgery	267	1.0	0.7–1.2
Observation care only	14,126	50.6	49.3–51.9
Other treatment[C]	81	0.3	0.1–0.5
Discharge status			
Routine discharge from ED	20,992	75.1	74.0–76.2
Admission to hospital	6136	22.0	20.9–23.0
Transferred to other medical facility	464	1.7	1.4–2.0
Left against medical advice	277	1.0	0.8–1.3
Other or unknown	57	0.2	0.1–0.4
Death	15	0.05	0.02–0.2

ED emergency department, *IV* intravenous
[A]Minor incident includes all other incidents that involved an abortion-related diagnosis or treatment, such as those requiring medication or repeat procedure
[B]Major incident includes those requiring overnight inpatient stay, blood transfusion, or surgery
[C]Other treatments include suture of laceration to the cervix, laminaria insertion, and abscess drainage

5.6%), abortion-related surgery (1.0%, 95% CI 0.7–1.2%), or other treatments (0.3%, 95% CI 0.2–0.5%), and 19.4% (95% CI 18.5–20.5%) of all abortion-related visits resulted in an overnight inpatient stay at the same hospital. Major incidents, treated with blood transfusion, surgery, or overnight inpatient stay, accounted for 20.3% (95% CI 19.3–21.3%) of all visits. Minor incidents accounted for 36.1% (95% CI 34.9–37.4%) of visits.

Three-quarters (75.1%) of abortion-related ED visits resulted in discharge from the ED. Another 21.2% were admitted to the same hospital for abortion-related reasons and 0.8% were admitted for non-abortion-related reasons. For the remaining 3%, the disposition was unknown or they were transferred to another medical facility or left against medical advice. Among all abortion-related ED visits over the 5 years of data ($n = 27,941$), 15 ended in the patient's death.

Several demographic and hospital factors were significantly associated with major incidents in a multivariable model (Table 3). Women over 30 were more likely than women aged 20–24 to have major incidents ($P < 0.001$), and women using Medicaid ($P = 0.004$) were more likely than women with private insurance to have a major incident. Women who paid out of pocket for the ED visit were less likely to have a major incident than women with private insurance ($P = 0.001$). The presence of any of the three examined comorbid conditions was associated with more than double the odds of a major incident compared to women without those comorbid conditions ($P < 0.01$). ED visits at trauma hospitals were more likely to be for major incidents than those at non-trauma hospitals ($P < 0.001$). ED visits in all regions were significantly more likely to be for a major incident than those in the Midwest ($P < 0.001$). There was a decreasing trend in major incidents over time. Similar significant relationships were found for factors associated with receipt of observation care only, but factors associated with increased likelihood of major incidents were associated with a lower likelihood of requiring observation care only. Two notable exceptions are a significantly higher likelihood of observation care only in the West compared to the Midwest ($P < 0.001$) and the absence of a trend over time for receipt of observation care only.

We used published rates of the total number of abortions to calculate the percentage of all abortions seen in an ED that resulted in a major incident. During the 5-year study period, there were an estimated 5,282,500 total abortions in the U.S. [17]. Using this number as the denominator, we estimate the rate of major incidents seen in EDs for abortion in the U.S. is 0.11%, or 108 per 100,000 abortions.

We identified 390 ED visits that represented potential self-induced abortion and accounted for 1.4% of abortion-related ED visits during the study period (95% CI 1.1–1.7%). There were slightly higher rates of potential self-induced abortion in the South (2.0%) than in the Midwest (1.0%), West (1.1%), and Northeast (1.3%) ($P = 0.05$) (Table 4). There were no time trends or other factors associated with self-induced abortion.

Discussion

We found that abortion-related ED visits comprised 0.01% of ED visits among women aged 15–49. In other

Table 3 Factors associated with major incidents and observation care only, weighted $n = 27,941$

	Major incident	Observation care
	Adjusted odds ratio (95% confidence interval)	Adjusted odds ratio (95% confidence interval)
Age		
15–19	0.94 (0.74–1.21)	1.18 (0.97–1.42)
20–24	Reference	Reference
25–29	1.08 (0.91–1.28)	0.81** (0.71–0.94)
30–39	1.49*** (1.24–1.79)	0.72*** (0.62–0.83)
40–49	1.75** (1.21–2.53)	0.55*** (0.39–0.77)
Primary payer		
Private insurance	Reference	Reference
Medicaid	1.28** (1.08–1.52)	0.83* (0.72–0.96)
Medicare	1.30 (0.79–2.15)	0.94 (0.55–1.62)
Self-pay	0.66** (0.52–0.85)	1.33** (1.12–1.57)
No charge	1.20 (0.39–3.69)	0.73 (0.34–1.59)
Other	1.35 (0.93–1.97)	0.95 (0.68–1.31)
Missing	0.32 (0.06–1.70)	0.85 (0.36–2.00)
Urban/rural residence		
Urban	Reference	Reference
Rural	1.02 (0.59–1.75)	0.86 (0.58–1.28)
Missing	1.67 (0.58–4.75)	0.43 (0.14–1.28)
Zip code-based income quartile		
First quartile	Reference	Reference
Second quartile	1.11 (0.90–1.36)	0.95 (0.82–1.10)
Third quartile	0.93 (0.75–1.15)	0.89 (0.76–1.04)
Fourth quartile	1.04 (0.82–1.32)	0.92 (0.77–1.11)
Missing	0.90 (0.46–1.75)	0.96 (0.54–1.70)
Diabetes indicated		
No	Reference	Reference
Yes	2.47** (1.42–4.31)	0.28*** (0.14–0.54)
Hypertension indicated		
No	Reference	Reference
Yes	3.79*** (2.46–5.83)	0.52** (0.34–0.80)
Overweight/obese BMI indicated		
No	Reference	Reference
Yes	4.63*** (2.65–8.10)	0.18*** (0.10–0.33)
Hospital characteristics		
Region		
Northeast	1.89*** (1.32–2.71)	0.65** (0.48–0.88)
Midwest	Reference	Reference
South	2.11*** (1.53–2.90)	0.69** (0.54–0.86)
West	1.80*** (1.30–2.49)	2.19*** (1.71–2.80)
Trauma level of hospital		
Level I or II	1.52*** (1.23–1.88)	0.81* (0.68–0.98)
Nontrauma or level III	Reference	Reference
Not specified	1.40 (0.88–2.23)	0.86 (0.55–1.35)
Urban or rural location of hospital		
Urban	Reference	Reference
Rural	0.65 (0.36–1.17)	1.20 (0.77–1.86)
Year		
2009	Reference	Reference
2010	0.85 (0.68–1.07)	1.04 (0.85–1.28)
2011	0.77* (0.61–0.98)	1.09 (0.88–1.36)
2012	0.73** (0.57–0.92)	0.95 (0.76–1.19)
2013	0.71** (0.56–0.90)	0.87 (0.70–1.08)

* $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$
BMI body mass index

words, 14 of every 100,000 ED visits among women aged 15–49 were for abortion-related reasons. The majority (51%) of these were visits involving observation care only.

These data also allowed us to estimate the national major incident rate after an abortion. The rate of 0.11% (108 per 100,000) abortion patients is slightly higher than the rate of 0.05% found in a study of first trimester abortion patients in California [18], and slightly lower than the rate of 0.23% found in a study of all abortions covered by California's Medicaid program [2]. While not all abortion-related incidents lead to an ED visit and thus, are not reflected in this estimate, we believe that the vast majority of major incidents (those involving a blood transfusion, surgery, or hospital admission) are reflected here. Those that would be missed from this analysis are cases that skip the ED and are directly admitted to a hospital or an outpatient surgicenter (usually for scheduled hospitalization) and complications arising from the small proportion (4%) of abortions done in hospitals [17] and are then directly admitted. Thus, the major incident rate may be slightly underestimated.

The major incident rate for abortion (0.1%) is lower than the published rates for pregnancy (1.4%) [19], as well as other common procedures such as colonoscopy (0.2%) [20], wisdom tooth removal (1.0%) [21], and tonsillectomy (1.4%) [22]. Abortion care is, thus, safer than many other unregulated outpatient procedures. Additionally, we found 15 deaths between 2009 and 2013, which is slightly lower than the total number of abortion-related deaths reported in 2009–2012, the most recent years available ($n = 24$) [23].

Notably, the majority of visits involved observation care only, which is consistent with a previous study [2].

Table 4 Potential self-induced abortion, by region

	Weighted *N*	Weighted percentage of all abortion-related emergency department visits	Weighted percentage 95% confidence interval	Chi-squared test *P* value
Overall	390	1.4	1.1–1.7	
Region				0.048
Northeast	58	1.3	0.7–2.2	
Midwest	44	1.0	0.5–1.9	
South	195	2.0	1.5–2.6	
West	94	1.1	0.7–1.6	

Patients experience a range of post-abortion symptoms, including ongoing uterine cramping and bleeding for up to 3 weeks after the abortion. Patients may not realize that this is normal. Some women do not start to bleed until several days after the abortion, while some stop bleeding and then start again. Increased cramping and bleeding could start several days after the abortion. Patients may not be given ample information about what to expect or they may have trouble differentiating normal post-abortion symptoms from signs of a complication. Patient visits to EDs for non-urgent care have the potential to be costly to the health system. Such visits could be due to several reasons and little research has been done on factors that contribute to patients' decisions to visit an ED after abortion. EDs offer 24-h access to care compared to abortion facilities, which have relatively limited hours and may require an appointment [24]. The long distances that many women across the U.S. must travel to reach an abortion provider may make return visits for follow-up too arduous [25, 26]. Indeed, research found that patients who travel longer distances to reach an abortion provider are more likely to visit an ED for follow-up care or to manage subsequent symptoms and less likely to return to the original abortion provider [27]. We note that patients presenting to the ED were disproportionately of urban residence (91% in the sample compared to 81% of the U.S. population) [28]. This is likely explained in that 91% of abortion patients live in urban areas [29] and 92% of EDs in the sample were in urban areas, attracting mainly local residents who may find them convenient geographically.

Post-abortion visits to the ED may also be driven by stigma, worry, or distrust of abortion providers. A perception that abortion is unsafe [30–32] may lead women to worry about mild symptoms, such as cramping and bleeding, even though they are an expected result of abortion. Such perceptions may stem from abortion portrayals in the media and popular culture. A study of abortion-related storylines in fictional American television shows found a major incident rate of 34% [33], over 34,000% greater than the real-life major incident rate of 0.1% found here. The long-term consequences of these fictional abortions were much more likely to be severe, including frequent depictions of negative mental health sequelae, infertility, and even death.

Women using Medicaid had higher odds of major incidents than those not using Medicaid and lower odds of observation care. In this context, insurance type may be a proxy for socioeconomic status, as women requiring Medicaid are low income and as a result, face a multitude of barriers to accessing health care and are known to have poorer health status, including multiple chronic conditions, than women with private insurance. Women who were self-pay were less likely to have major incidents and more likely to receive observation care only, suggesting that patients without healthcare coverage may not have been given treatments to reduce patient costs.

We found that the pre-existing chronic conditions that have previously been suspected to be associated with major abortion-related incidents were indeed associated with a significantly higher rate of those incidents in this sample. While there is limited previous research on the impact of chronic health conditions on the risk of abortion complications, it is well established that women with chronic conditions are more likely to have pregnancy-related complications [34]. Our findings are consistent with provider guidance that suggests women with multiple chronic medical conditions may be at increased risk [35], but conflicting with previous studies that find that obesity and chronic health conditions confer no increased risk among women having abortions [11–14]. This increased risk might be explained in that women who had overnight inpatient stays (one of the categories of a major incident) were more likely to have their obesity or other chronic diseases documented in their charts than those who did not have an overnight stay.

We found some cases of potential self-induced abortions using such means as poisoning or other methods of self-harm. While self-induced abortions are safe when appropriate dosages of mifepristone and misoprostol or misoprostol alone are used, other methods are hazardous, as evidenced by ED visits. Rates were highest in the South, which is known to have the most barriers to abortion access, including the fewest providers [17, 26],

and the most state-level restrictions. States that are hostile to abortion may see more ED visits due to self-induced abortion than non-hostile states, potentially due to stigma, protesters, and other barriers to in-clinic abortion.

This study included a large, nationally representative sample of ED visits, allowing us to draw national- and regional-level conclusions about abortion safety. However, using billing codes to understand the nature of the ED visit can be imprecise and incomplete. The estimates produced here may be conservative if patients did not report having had an abortion due to fear of stigmatization or if relevant diagnosis and procedure codes were not reported or were systematically misreported. The lack of full clinical data to determine abortion relatedness could cause errors. For example, the visits in this study could include cases of miscarriage. Likewise, this study may miss abortion-related incidents that were inaccurately coded as a miscarriage.

Conclusions

These new findings can inform policy debates regarding abortion regulation in the U.S. Regulations on abortion provider or facility relationships to hospitals or EDs should be considered in light of their relative impact on improving women's health. Because abortion-related ED visits comprise a very small proportion of women's ED visits, and the rate of major incidents is very low, regulations on abortion are unlikely to have any impact on women's health outcomes. Many abortion-related ED visits are for observation only and may not be indicated or could be managed at a less costly level of care. Perceptions that abortion is unsafe are not based on evidence.

Abbreviations

AOR: Adjusted odds ratio; BMI: Body mass index; CI: Confidence interval; CPT: Current Procedural Terminology; ED: Emergency department; HCPCS: Healthcare Common Procedure Coding System; HCUP: Healthcare Cost and Utilization Project; ICD-9: International Classification of Diseases, 9th Revision; IV: Intravenous; NEDS: Nationwide Emergency Department Sample; PAIRS: Procedural Abortion Incident Reporting and Surveillance; U.S.: United States

Funding

This work was supported by a research grant to UDU from the Society of Family Planning (grant SFPRF10). The funder had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Availability of data and materials

The HCUP databases are available for purchase online through the HCUP Central Distributor. More information is available here: https://www.hcup-us.ahrq.gov/tech_assist/centdist.jsp.

Authors' contributions

UDU, NEJ, and AFC conceived and designed the study. NEJ acquired the data and led the data analysis. RB, CT, AM, and AJM conducted the review and analysis of records. NEJ and UDU drafted the manuscript. All authors contributed to interpretation of the data, revised the draft manuscript for important intellectual content, and approved the final version.

Ethics approval and consent to participate

This study was approved by the institutional review board of the University of California, San Francisco (16-20371).

Consent for publication

No consent for publication was required.

Competing interests

The authors declare that they have no competing interests.

Publisher's Note

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Received: 1 February 2018 Accepted: 10 May 2018
Published online: 14 June 2018

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